

US3182292 (Prod: Rapid Medical Research Inc - ERN-PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:01:25

All time stamps listed in this document are displayed in GMT

US3182292

Form: Participant Creation

Data signed: (b) (4) 09 Mar 2021 04:48:54

Generated On: 11 Aug 2021 22:01:25

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[Participant ID](#)

US3182292

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

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US3182292

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:50:40

Generated On: 11 Aug 2021 22:01:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 19:50:39

Generated On: 11 Aug 2021 22:01:25

Date of Birth (MMM yyyy)	(b) (6) 2001
Age	19
Age Units	YEARS
Age (Derived)	19
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 19:50:39

Generated On: 11 Aug 2021 22:01:25

Date of Informed Consent ( <i>dd MMM yyyy</i> )	11 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) 15 Feb 2021 19:50:40

Generated On: 11 Aug 2021 22:01:25

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 19:50:40

Generated On: 11 Aug 2021 22:01:25

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Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 19:50:40

Generated On: 11 Aug 2021 22:01:25

Condition	CROHNS DISEASE
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 19:50:40

Generated On: 11 Aug 2021 22:01:25

Condition	COLITIS
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 19:50:40

Generated On: 11 Aug 2021 22:01:25

Condition	RIGHT ARM FRACTURE
Start date (dd MMM yyyy)	UN MAY 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JUL 2006
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2006
Start Year (derived)	2006
Stop Month and Year (derived)	JUL 2006
Stop Year (derived)	2006

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 19:50:40

Generated On: 11 Aug 2021 22:01:25

Condition	RIGHT ARM FRACTURE SURGICALLY REPAIRED
Start date (dd MMM yyyy)	UN MAY 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN MAY 2006
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2006
Start Year (derived)	2006
Stop Month and Year (derived)	MAY 2006
Stop Year (derived)	2006

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 19:50:40

Generated On: 11 Aug 2021 22:01:25

Condition	RIGHT ARM FRACTURE
Start date (dd MMM yyyy)	UN MAY 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN MAY 2020
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	MAY 2020
Stop Year (derived)	2020

US3182292

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 19:50:40

Generated On: 11 Aug 2021 22:01:25

Condition	RIGHT ARM FRACTURE SURGICAL REPAIR
Start date (dd MMM yyyy)	UN MAY 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN MAY 2020
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	MAY 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 19:50:40

Generated On: 11 Aug 2021 22:01:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	14:30 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 14:30
Height (xxx.x)	179.6 cm
Weight (xxx.x)	65.7 kg
BMI (xxx.x)	20.36820 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) 15 Feb 2021 19:50:40

Generated On: 11 Aug 2021 22:01:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 19:50:40

Generated On: 11 Aug 2021 22:01:25

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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) EMPLOYEE

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

**No Risk Identified** False

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



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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 19:50:40

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:24:29

Generated On: 11 Aug 2021 22:01:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 19:24:29

Generated On: 11 Aug 2021 22:01:25

What was the date of randomization? (dd MMM yyyy) 11 AUG 2020

What was the participant's randomization number? 103147

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) 15 Feb 2021 19:24:29

Generated On: 11 Aug 2021 22:01:25

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 19:24:29

Generated On: 11 Aug 2021 22:01:25

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)	11 AUG 2020
Time of assessment (00:00-23:59)	14:30 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 14:30
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 19:24:29

Generated On: 11 Aug 2021 22:01:25

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)	11 AUG 2020
Time of assessment (00:00-23:59)	16:17 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 16:17
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:24:29

Generated On: 11 Aug 2021 22:01:25

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 19:24:29

Generated On: 11 Aug 2021 22:01:25

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) 11 AUG 2020

What was the treatment time? (00:00-23:59) 15:42 (24 HR)

Treatment Date and Time (derived) 11 AUG 2020 15:42

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

What was the frequency of the study treatment dosing? ONCE

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



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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:24:29

Generated On: 11 Aug 2021 22:01:25

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 AUG 2020

Collection time (00:00-23:59)

15:20 (24 HR)

Collection date and time (derived)

11 AUG 2020 15:20

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 19:24:28

Generated On: 11 Aug 2021 22:01:25

Collection date (dd MMM yyyy)			11 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:15	11 AUG 2020 15:15
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:24:29

Generated On: 11 Aug 2021 22:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:01:25

**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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 16:10

PC Open Date & Time

11 AUG 2020 16:02

PC Close Date & Time

11 AUG 2020 18:32

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:01:25

**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	11 AUG 2020 22:57
PC Open Date & Time	11 AUG 2020 19:27
PC Close Date & Time	12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 13:20

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:01:25

**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

95.9 °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

13 AUG 2020 17:58

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:01:25

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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

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

14 AUG 2020 17:19

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59



US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	96.9 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

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

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:01:25

**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

97.4 °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

16 AUG 2020 22:30

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:01:25

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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

98.1 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

17 AUG 2020 17:45

---

PC Open Date & Time

17 AUG 2020 12:00

---

PC Close Date & Time

18 AUG 2020 11:59

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US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:01:25

**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

11 AUG 2020 16:11

PC Open Date & Time

11 AUG 2020 16:02

PC Close Date & Time

11 AUG 2020 18:32

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:01:25

**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 ☐

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

5

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

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 22:59

PC Open Date & Time

11 AUG 2020 19:27

PC Close Date & Time

12 AUG 2020 11:59

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:01:25

**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 ☐

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

5

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

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

Yes ☐

No ☒

Please record - **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

12 AUG 2020 13:20

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:01:25

**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

13 AUG 2020 17:58

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:01:25

**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

14 AUG 2020 17:18

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59



US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:01:25

**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

16 AUG 2020 00:00

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:01:25

**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

16 AUG 2020 22:30

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:01:25

**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

17 AUG 2020 17:45

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:01:25

**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 ☐

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:01:25

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 16:11
PC Open Date & Time	11 AUG 2020 16:02
PC Close Date & Time	11 AUG 2020 18:32

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:01:25

**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 ☐

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:01:25

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 22:59
PC Open Date & Time	11 AUG 2020 19:27
PC Close Date & Time	12 AUG 2020 11:59

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:01:25

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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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:01:25

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 13:21
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:01:25

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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US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:01:25

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 17:58
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:01:25

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 ☒

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:01:25

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 17:18
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:01:25

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:01:25

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

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:01:25

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 ☒



US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:01:25

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 22:30
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:01:25

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)

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:01:25

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 17:46
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3182292

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:35:45

Generated On: 11 Aug 2021 22:01:25

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3182292

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:35:45

Generated On: 11 Aug 2021 22:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182292

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:35:45

Generated On: 11 Aug 2021 22:01:25

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 UNDER COVD  
SURVEILLANCE AND  
RECEIVING DAILY  
TELEMEDICINE CALLS DURING  
THIS TIME FRAME.

US3182292

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:35:45

Generated On: 11 Aug 2021 22:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182292

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:35:45

Generated On: 11 Aug 2021 22:01:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3182292

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:35:45

Generated On: 11 Aug 2021 22:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182292

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:24:29

Generated On: 11 Aug 2021 22:01:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 19:24:29

Generated On: 11 Aug 2021 22:01:25

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)	10 SEP 2020
Time of assessment (00:00-23:59)	11:47 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 11:47
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	47 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	61 mmHg
Diastolic Blood Pressure units	MMHG

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 19:24:29

Generated On: 11 Aug 2021 22:01:25

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	

US3182292

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:24:29

Generated On: 11 Aug 2021 22:01:25

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.*

US3182292

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 19:24:29

Generated On: 11 Aug 2021 22:01:25

Was study treatment given? Yes ☐  
No ☒

If No, reason not given

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

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

What was the study treatment?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3182292

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:24:29

Generated On: 11 Aug 2021 22:01:25

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 SEP 2020

Collection time (00:00-23:59)

12:00 (24 HR)

Collection date and time (derived)

10 SEP 2020 12:00

US3182292

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 19:24:29

Generated On: 11 Aug 2021 22:01:25

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:42	10 SEP 2020 11:42
Nasopharyngeal Swab 2	No		



US3182292

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:24:29

Generated On: 11 Aug 2021 22:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182292

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:35:45

Generated On: 11 Aug 2021 22:01:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3182292

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:35:45

Generated On: 11 Aug 2021 22:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182292

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:24:28

Generated On: 11 Aug 2021 22:01:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3182292

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:24:28

Generated On: 11 Aug 2021 22:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182292

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:24:28

Generated On: 11 Aug 2021 22:01:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3182292

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:24:28

Generated On: 11 Aug 2021 22:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182292

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:24:29

Generated On: 11 Aug 2021 22:01:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 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



US3182292

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 19:24:29

Generated On: 11 Aug 2021 22:01:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 OCT 2020
Time of assessment (00:00-23:59)	11:15 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 11:15
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3182292

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:24:29

Generated On: 11 Aug 2021 22:01:25

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.*

US3182292

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:24:29

Generated On: 11 Aug 2021 22:01:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 OCT 2020
Collection time (00:00-23:59)	11:23 (24 HR)
Collection date and time (derived)	8 OCT 2020 11:23

US3182292

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:24:29

Generated On: 11 Aug 2021 22:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182292

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 OCT 2020 18:16:53
Patient Cloud Open Date & Time	11 OCT 2020 00:01
Patient Cloud Close Date & Time	15 OCT 2020 23:59

US3182292

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**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

18 OCT 2020 03:57:20

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3182292

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 OCT 2020 00:01:42

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3182292

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 17:59:38

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59



US3182292

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 NOV 2020 00:16:19

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 00:04:39
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 12:00:37
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 00:45:47
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 DEC 2020 00:05:56
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 DEC 2020 00:09:23

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59



US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**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

31 DEC 2020 09:32:19

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 JAN 2021 12:05:24
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 JAN 2021 00:01:29
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 JAN 2021 12:00:36
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**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

28 JAN 2021 00:01:26

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 00:01:48
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 FEB 2021 00:01:16
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**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

18 FEB 2021 00:18:24

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59



US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 FEB 2021 05:02:20
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**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

04 MAR 2021 00:03:00

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**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

11 MAR 2021 00:02:27

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**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

18 MAR 2021 00:08:16

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**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

25 MAR 2021 00:03:10

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 APR 2021 12:02:13
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**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

11 APR 2021 17:59:13

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**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

15 APR 2021 00:28:46

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59



US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 00:02:27

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 00:02:22

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

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[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

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US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

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[Patient Cloud Close Date & Time](#)

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17 MAY 2021 23:59

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US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

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[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

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US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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 <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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

27 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

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US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

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[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

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US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59



US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

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[Patient Cloud Close Date & Time](#)

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28 JUN 2021 23:59

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US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 JUL 2021 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

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

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

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[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

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US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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



US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**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 ☐

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

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[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

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US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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°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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

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[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

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US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

16 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

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US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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="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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59



US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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="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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

28 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

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US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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 <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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59



US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

11 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

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US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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 <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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

02 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

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US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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 <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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

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[Patient Cloud Close Date & Time](#)

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27 DEC 2021 23:59

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US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**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 ☐

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59



US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**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 ☐

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**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 ☐

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59



US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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="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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	03 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 FEB 2022 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

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[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

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US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

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

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59



US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

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

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

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

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

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[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

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US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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 <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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**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 ☐

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

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[Patient Cloud Close Date & Time](#)

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28 MAR 2022 23:59

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US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

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[Patient Cloud Open Date & Time](#)

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14 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 APR 2022 23:59

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US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59



US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

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[Patient Cloud Open Date & Time](#)

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05 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAY 2022 23:59

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US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

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[Patient Cloud Close Date & Time](#)

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16 MAY 2022 23:59

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US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

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[Patient Cloud Close Date & Time](#)

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23 MAY 2022 23:59

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US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

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[Patient Cloud Close Date & Time](#)

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30 MAY 2022 23:59

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US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**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 ☐

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

02 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

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US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**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 ☐

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59



US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**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 ☐

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

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

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

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

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59



US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JUL 2022 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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="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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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 <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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59



US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**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 ☐

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

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[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

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US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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 <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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

22 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

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US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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 <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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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

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

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

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[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

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US3182292

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

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"/>

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	13 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 OCT 2022 23:59
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US3182292

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:01:25

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		04 MAR 2021 00:03:07

US3182292

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:48:56

Generated On: 11 Aug 2021 22:01:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3182292

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:48:56

Generated On: 11 Aug 2021 22:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182292

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:48:56

Generated On: 11 Aug 2021 22:01:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3182292

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:48:56

Generated On: 11 Aug 2021 22:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182292

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:48:56

Generated On: 11 Aug 2021 22:01:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3182292

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:48:56

Generated On: 11 Aug 2021 22:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182292

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:48:56

Generated On: 11 Aug 2021 22:01:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3182292

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:48:56

Generated On: 11 Aug 2021 22:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182292

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 04:48:56

Generated On: 11 Aug 2021 22:01:25

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

Visit date (dd MMM yyyy)	23 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
------------	--------

US3182292

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 14:55:23

Generated On: 11 Aug 2021 22:01:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 FEB 2021
Time of assessment (00:00-23:59)	12:49 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 12:49
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3182292

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 04:48:56

Generated On: 11 Aug 2021 22:01:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 FEB 2021

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

US3182292

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 11 Mar 2021 22:15:26

Generated On: 11 Aug 2021 22:01:25

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 FEB 2021

Collection time (00:00-23:59)

13:05 (24 HR)

Collection date and time (derived)

23 FEB 2021 13:05

US3182292

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:48:56

Generated On: 11 Aug 2021 22:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3182292

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:15:27

Generated On: 11 Aug 2021 22:01:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3182292

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:15:27

Generated On: 11 Aug 2021 22:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3182292**

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

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:01:25**

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*

**US3182292**

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

**Form: Continuing**

**Generated On: 11 Aug 2021 22:01:25**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID-19 Contact

Data signed: (b) (4) 09 Mar 2021 04:48:54

Generated On: 11 Aug 2021 22:01:25

Date of Contact	25 AUG 2020
Time of Contact	10:30
Date and Time of Contact (derived)	25 AUG 2020 10:30
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>

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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"/>

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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

Date	23 AUG 2020
------	-------------

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

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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



US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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 ☐

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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"/>

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 AUG 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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"/>

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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

Date	25 AUG 2020
------	-------------

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

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	101.6 F
-------------	---------

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

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

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

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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



US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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 ☐

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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"/>

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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

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EAB) (1725)

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US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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 ☐

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

Symptom Day

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (5)

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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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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

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Generated On: 11 Aug 2021 22:01:25

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 25 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

Symptom Day

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

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Form: Symptom Log (6)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	99.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

	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 25 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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

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Form: Symptom Log (7)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

Symptom Day

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

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Form: Symptom Log (7)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 AUG 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Generated On: 11 Aug 2021 22:01:25

	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 (7)

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Generated On: 11 Aug 2021 22:01:25

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 (8)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

Symptom Day

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

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Form: Symptom Log (8)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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

Date	30 AUG 2020
------	-------------

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

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

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

Temperature	97.9 F
-------------	--------

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

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

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

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

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Form: Symptom Log (8)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

	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 25 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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 ☐

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

Symptom Day

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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

Date	31 AUG 2020
------	-------------

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

O2 Saturation	94 %
---------------	------

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

Temperature	98.5 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

	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"/>



US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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"/>

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

Symptom Day

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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

Date	01 SEP 2020
------	-------------

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

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

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

Temperature	98.0 F
-------------	--------

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

Cough	None <input 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 25 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

	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"/>

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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 25 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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 25 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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

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

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

O2 Saturation	94 %
---------------	------

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

Temperature	98.5 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

	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 25 Aug 2020

Form: Symptom Log (11)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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 25 Aug 2020

Form: Symptom Log (12)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

Symptom Day

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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

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

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

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

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

Temperature	99.0 F
-------------	--------

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

Cough	None <input 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 25 Aug 2020

Form: Symptom Log (12)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

	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 25 Aug 2020

Form: Symptom Log (12)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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 25 Aug 2020

Form: Symptom Log (13)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

Symptom Day

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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

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

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

O2 Saturation	95 %
---------------	------

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

Temperature	99.0 F
-------------	--------

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

Cough	None	<input 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 25 Aug 2020

Form: Symptom Log (13)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

	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 25 Aug 2020

Form: Symptom Log (13)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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 25 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

Symptom Day

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	05 SEP 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 25 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

	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 25 Aug 2020

Form: Symptom Log (14)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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 ☐

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

Symptom Day

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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

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

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

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

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

Temperature	97.9 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

	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 25 Aug 2020

Form: Symptom Log (15)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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 ☐

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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

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

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

O2 Saturation	94 %
---------------	------

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

Temperature	96.9 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

	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 25 Aug 2020

Form: Symptom Log (16)

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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 25 Aug 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 09 Mar 2021 04:48:54

Generated On: 11 Aug 2021 22:01:25

Date of Visit	25 AUG 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	25 AUG 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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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

If Yes, provide:

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

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

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

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

If Yes, provide:

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

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

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

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

If Yes, provide:

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

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

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

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

If Yes, provide:

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

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

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

Did the subject have Respiratory failure? Yes ☐ No ☒

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

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

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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

**Ventilator Support:**

High-Flow Oxygen? Yes ☐  
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐  
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐  
No ☐

Start Date

End Date

ECMO? Yes ☐  
No ☐

Start Date

End Date

**Evidence of Shock:**

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

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐  
No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐  
No ☒

Start Date

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 09 Mar 2021 04:48:55

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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

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

---

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	27 AUG 2020
Day 5	Yes	29 AUG 2020
Day 7	Yes	31 AUG 2020
Day 9	Yes	2 SEP 2020
Day 14	Yes	7 SEP 2020
Day 21	Yes	14 SEP 2020
Day 28	Yes	22 SEP 2020

US3182292

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 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	SICKD1

US3182292

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 AUG 2020
Time of assessment (00:00-23:59)	15:00 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 15:00
Height (xxx.x)	179.6 cm
Weight (xxx.x)	65.7 kg
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3182292

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 AUG 2020

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

US3182292

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

25 AUG 2020

US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 04:48:54

Generated On: 11 Aug 2021 22:01:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28



US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Mar 2021 04:48:54

Generated On: 11 Aug 2021 22:01:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 SEP 2020
Time of assessment (00:00-23:59)	15:07 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 15:07
Height (xxx.x)	179.6 cm
Weight (xxx.x)	65.4 kg
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 04:48:54

Generated On: 11 Aug 2021 22:01:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 SEP 2020

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

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Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 09 Mar 2021 04:48:54

Generated On: 11 Aug 2021 22:01:25

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

22 SEP 2020

US3182292

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

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 04:48:56

Generated On: 11 Aug 2021 22:01:25

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

Visit date (dd MMM yyyy)	23 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

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

Form: Unblinding

Data signed: (b) (4) 11 Mar 2021 22:15:26

Generated On: 11 Aug 2021 22:01:25

Date of updated informed consent ( <i>dd MMM yyyy</i> )	23 FEB 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> )	23 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3182292

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 09 Mar 2021 04:48:56

Generated On: 11 Aug 2021 22:01:25

Height	179.6 cm
Weight	65.7 kg
BMI (xxx.x)	20.36820

US3182292

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Mar 2021 04:48:56

Generated On: 11 Aug 2021 22:01:25

Height	179.6 cm
Weight	65.7 kg
BMI (xxx.x)	20.36820
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 FEB 2021
Time of assessment (00:00-23:59)	12:49 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 12:49
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3182292

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Mar 2021 04:48:56

Generated On: 11 Aug 2021 22:01:25

Height	179.6 cm
Weight	65.7 kg
BMI (xxx.x)	20.36820
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 FEB 2021
Time of assessment (00:00-23:59)	14:22 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 14:22
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG



US3182292

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

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 04:48:56

Generated On: 11 Aug 2021 22:01:25

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

23 FEB 2021

---

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

---

US3182292

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

Form: Exposure

Data signed: (b) (4) 09 Mar 2021 04:48:56

Generated On: 11 Aug 2021 22:01:25

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

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

What was the treatment time? (00:00-23:59) 13:52 (24 HR)

Treatment Date and Time (derived) 23 FEB 2021 13:52

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

US3182292

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 04:48:56

Generated On: 11 Aug 2021 22:01:25

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

Collection date (dd MMM yyyy)	23 FEB 2021
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Collection time (00:00-23:59)	13:05 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	23 FEB 2021 13:05
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US3182292

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Mar 2021 04:48:56

Generated On: 11 Aug 2021 22:01:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 FEB 2021
Collection time (00:00 - 23:59)	12:54
Collection Date and Time (derived)	23 FEB 2021 12:54

US3182292

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

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:48:56

Generated On: 11 Aug 2021 22:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182292

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Mar 2021 15:38:22

Generated On: 11 Aug 2021 22:01:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3182292

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 18 Mar 2021 15:38:22

Generated On: 11 Aug 2021 22:01:25

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

US3182292

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 13:20:44

Generated On: 11 Aug 2021 22:01:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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	OLD29



US3182292

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 13:20:44

Generated On: 11 Aug 2021 22:01:25

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 MAR 2021
Time of assessment (00:00-23:59)	11:55 (24 HR)
Vital Signs Date and Time (derived)	23 MAR 2021 11:55
Temperature (xxx.x)	98.1 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)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3182292

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Mar 2021 13:20:44

Generated On: 11 Aug 2021 22:01:25

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 MAR 2021
Time of assessment (00:00-23:59)	12:50 (24 HR)
Vital Signs Date and Time (derived)	23 MAR 2021 12:50
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)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3182292

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 13:20:44

Generated On: 11 Aug 2021 22:01:25

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

23 MAR 2021

---

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

---

US3182292

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 26 Mar 2021 13:20:44

Generated On: 11 Aug 2021 22:01:25

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

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

What was the treatment time? (00:00-23:59) 12:19 (24 HR)

Treatment Date and Time (derived) 23 MAR 2021 12:19

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

US3182292

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 13:20:44

Generated On: 11 Aug 2021 22:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182292

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 15:50:44

Generated On: 11 Aug 2021 22:01:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3182292

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 15:50:44

Generated On: 11 Aug 2021 22:01:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182292

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Apr 2021 11:55:24

Generated On: 11 Aug 2021 22:01:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 APR 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



US3182292

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Apr 2021 11:55:24

Generated On: 11 Aug 2021 22:01:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	20 APR 2021
Time of assessment ( <i>00:00-23:59</i> )	11:40 (24 HR)
Vital Signs Date and Time (derived)	20 APR 2021 11:40
Temperature ( <i>xxx.x</i> )	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	82 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3182292

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Apr 2021 11:55:24

Generated On: 11 Aug 2021 22:01:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 APR 2021

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

US3182292

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Apr 2021 11:55:24

Generated On: 11 Aug 2021 22:01:25

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 APR 2021

Collection time (00:00-23:59)

11:48 (24 HR)

Collection date and time (derived)

20 APR 2021 11:48

US3182292

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 09 Mar 2021 04:48:54

Generated On: 11 Aug 2021 22:01:25

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3182292

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Mar 2021 03:45:33

Generated On: 11 Aug 2021 22:01:25

AEID	USA-US075-2020-MRNA-1273-P30 1000001
Adverse event	COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	23 AUG 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)	28 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3182292

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Mar 2021 03:45:33

Generated On: 11 Aug 2021 22:01:25

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 checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative DAYS 3, 5, 7 AND 9 SALIVA COLLECTION WERE POSITIVE. DAYS 14, 21 AND 28 WERE NEGATIVE.	
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)	
PRODUCTION RELEASE (v12.003 EAB) (1725)	
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US3182292

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Mar 2021 04:48:54

Generated On: 11 Aug 2021 22:01:25

---

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

Yes ☒

No ☐

---

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

---

US3182292

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Mar 2021 04:48:54

Generated On: 11 Aug 2021 22:01:25

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication POSITIVE COVID PCR

Dose per administration 400

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3182292

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Mar 2021 04:48:54

Generated On: 11 Aug 2021 22:01:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3182292

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Mar 2021 04:48:54

Generated On: 11 Aug 2021 22:01:25

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3182292

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:01:25

Visit	Screening	<input type="checkbox"/>
	Visit 1 Day 1	<input type="checkbox"/>
	Visit 2 Day 29	<input type="checkbox"/>
	Visit 3 Day 57	<input type="checkbox"/>
	Visit 4 Day 209	<input type="checkbox"/>
	Visit 5 Day 394	<input type="checkbox"/>
	Visit 6 Day 759	<input type="checkbox"/>

**Case Report Form**

Visit Date	
Demographics	
Enrollment	
Inclusion/Exclusion Criteria Summary	
Inclusion/Exclusion Criteria	
Medical History Summary	
Medical History	
Vital Signs	
Vital Signs - Dosing	
Physical Examination	
Central Laboratory - Nasopharyngeal Swab	
Childbearing Potential	
Pregnancy Test	
Randomization	
Exposure	
Immunogenicity Assessment	
Saliva Collection	
COVID Diagnostic Test	
Symptom Log	
Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection	
COVID-19 Severity Assessment	
COVID-19 Contact	
Risk of Exposure	
Safety Call	
Dosing Discontinuation	
End of Study / Study Discontinuation	

US3182292

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 11 Aug 2021 22:01:25

All	
Date of missed or out of window visit or assessment	
<b>Category</b>	
Inclusion criteria not met/Exclusion criteria met	
Study Treatment not given	
Missed Visit	
Missed Assessment	
Visit performed out of window	
Assessment performed out of window	
Scheduled clinical visit performed as home visit	
Other	
Other, specify	
<b>Description of Relationship to COVID-19</b>	
Clinical site closed	
Travel restrictions	
Quarantine due to COVID-19	
Possible exposure to COVID-19	
Exposure to COVID-19	
Presumption / confirmed COVID-19	
Symptoms of COVID-19	
Sponsor hold due to COVID-19	
Participant decision	

US3182292

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 09 Mar 2021 04:48:55

Generated On: 11 Aug 2021 22:01:25

Date of dosing discontinuation (dd MMM yyyy) 1 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

US3182292

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:01:25

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 ☐

US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 09 Mar 2021 04:48:56

Generated On: 11 Aug 2021 22:01:25

SAEID	USA-US075-2020-MRNA-1273-P301000001
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	MARY BETH
Investigator's Last Name	MANNING
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 09 Mar 2021 04:48:56

Generated On: 11 Aug 2021 22:01:25

SAEID	USA-US075-2020-MRNA-1273-P301000001
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	MARY BETH
Investigator's Last Name	MANNING
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	01/SEP/2020 15:01
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



US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 09 Mar 2021 04:48:56

Generated On: 11 Aug 2021 22:01:25

SAEID	USA-US075-2020-MRNA-1273-P301000001
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	MARY BETH
Investigator's Last Name	MANNING
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	12/OCT/2020 13:19
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

US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 09 Mar 2021 04:48:56

Generated On: 11 Aug 2021 22:01:25

SAEID	USA-US075-2020-MRNA-1273-P301000001
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	MARY BETH
Investigator's Last Name	MANNING
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	27/OCT/2020 14:42
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

US3182292 (Prod: Rapid Medical Research Inc - ERN-PPDS)

**US3182292**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 22:01:25**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Aug 2020 21:26:06
User entered 'US3182292'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 18:39:37

US3182292

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:35:45
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	11 Aug 2020 19:35:10

US3182292

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:35:45
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 18:39:38

US3182292

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:35:45
User entered 'Clinic (Clinic)'	Amy Maroun (b) (4) (b) (4)	11 Aug 2020 19:35:10

**US3182292**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:01:25**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered 'SCRN'	System	11 Aug 2020 19:35:10



US3182292

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:01:25

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:35:59
User entered (b) (6) 2001'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 18:39:40

US3182292

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:01:25

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:35:59
User entered '19'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:51:06

**US3182292**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:01:25**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered 'YEARS'	System	18 Aug 2020 17:51:06

**US3182292**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:01:25**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered '19'	System	11 Aug 2020 19:35:27

US3182292

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:01:25

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:35:59
User entered 'Male (M)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:51:06

US3182292

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:01:25

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:35:59
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:51:06

US3182292

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:01:25

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:35:59
User entered 'I'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:51:06

US3182292

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:01:25

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:35:59
User entered '0'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:51:06



US3182292

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:01:25

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:35:59
User entered '0'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:51:06

US3182292

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:01:25

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:35:59
User entered '0'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:51:06

US3182292

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:01:25

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:35:59
User entered '0'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:51:06

US3182292

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:01:25

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:35:59
User entered '0'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:51:06

US3182292

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:01:25

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:35:59
User entered empty.	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:51:06

US3182292

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:01:25

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:35:59
User entered '0'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:51:06

US3182292

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:01:25

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:35:59
User entered '0'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:51:06

US3182292

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:01:25

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:36:16
User entered '11 Aug 2020'	Amy Maroun (b) (4) (b) (4)	11 Aug 2020 19:35:27



US3182292

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:01:25

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered 'Aug 2020'	System	11 Aug 2020 19:35:27

**US3182292**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:01:25**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered '2020'	System	11 Aug 2020 19:35:27

US3182292

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:01:25

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:36:16
User entered 'Amendment 2 (2)'	Amy Maroun (b) (4) (b) (4)	11 Aug 2020 19:35:27

US3182292

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:01:25

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:36:16
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	11 Aug 2020 19:35:27

US3182292

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:01:25

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:36:16
User entered empty.	Amy Maroun (b) (4) (b) (4)	11 Aug 2020 19:35:27

US3182292

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:01:25

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:36:16
User entered empty.	Amy Maroun (b) (4) (b) (4)	11 Aug 2020 19:35:27

US3182292

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:01:25

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:36:16
User entered 'No (N)'	Amy Maroun (b) (4) (b) (4)	11 Aug 2020 19:35:27

US3182292

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:01:25

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:36:16
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 18:39:38



US3182292

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:01:25

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered 'I'	System	11 Aug 2020 19:35:32

US3182292

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:01:25

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:36:53
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	11 Aug 2020 19:35:32

US3182292

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:01:25

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:36:58
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:16

US3182292

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:01:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User coded data point as SOC: Gastrointestinal disorders, HLGIT: Gastrointestinal inflammatory conditions, HLT: Colitis (excl infective), PT: Crohn's disease, LLT: Crohn's disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 19:43:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 19:43:38
Data point term sent to Coder	System	18 Aug 2020 17:57:44
User entered 'Crohns Disease'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:28

US3182292

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:01:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered 'un UNK 2003'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:28

US3182292

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:01:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered '0'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:28

US3182292

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:01:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:28

US3182292

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:01:25

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered empty.	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:28



US3182292

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:01:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered '0'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:28

**US3182292**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:01:25**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered 'Jan 2003'	System	18 Aug 2020 17:57:28

**US3182292**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:01:25**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered '2003'	System	18 Aug 2020 17:57:28

**US3182292**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:01:25**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered empty.	System	18 Aug 2020 17:57:28

**US3182292**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:01:25**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered empty.	System	18 Aug 2020 17:57:28

US3182292

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:01:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User coded data point as SOC: Gastrointestinal disorders, HLGIT: Gastrointestinal inflammatory conditions, HLT: Colitis (excl infective), PT: Colitis, LLT: Colitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 19:43:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 19:43:38
Data point term sent to Coder	System	18 Aug 2020 17:57:47
User entered 'Colitis'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:37

US3182292

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:01:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered 'un UNK 2003'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:37

US3182292

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:01:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered '0'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:37



US3182292

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:01:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:37

US3182292

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:01:25

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered empty.	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:37

US3182292

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:01:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered '0'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:37

**US3182292**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:01:25**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered 'Jan 2003'	System	18 Aug 2020 17:57:37

**US3182292**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:01:25**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered '2003'	System	18 Aug 2020 17:57:37

**US3182292**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:01:25**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered empty.	System	18 Aug 2020 17:57:37

**US3182292**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:01:25**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered empty.	System	18 Aug 2020 17:57:37

US3182292

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:01:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Upper limb fracture, LLT: Arm fracture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 19:51:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 19:51:32
Data point term sent to Coder	System	18 Aug 2020 17:58:48
User entered 'Right arm fracture'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:54



US3182292

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:01:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered 'un May 2006'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:54

US3182292

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:01:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered '0'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:54

US3182292

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:01:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:54

US3182292

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:01:25

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered 'un Jul 2006'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:54

US3182292

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:01:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered '0'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:54

**US3182292**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:01:25**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered 'May 2006'	System	18 Aug 2020 17:57:54

**US3182292**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:01:25**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered '2006'	System	18 Aug 2020 17:57:54

**US3182292**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:01:25**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered 'Jul 2006'	System	18 Aug 2020 17:57:54



**US3182292**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:01:25**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered '2006'	System	18 Aug 2020 17:57:54

US3182292

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:01:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Fracture treatments (excl skull and spine), PT: Fracture treatment, LLT: Fracture repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:09:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:09:34
Data point term sent to Coder	System	18 Aug 2020 17:58:48
User entered 'Right arm fracture surgically repaired'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:58:26

US3182292

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:01:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered 'un May 2006'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:58:26

US3182292

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:01:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered '0'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:58:26

US3182292

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:01:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:58:26

US3182292

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:01:25

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered 'un May 2006'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:58:26

US3182292

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:01:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered '0'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:58:26

**US3182292**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:01:25**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered 'May 2006'	System	18 Aug 2020 17:58:26



**US3182292**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:01:25**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered '2006'	System	18 Aug 2020 17:58:26

**US3182292**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:01:25**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered 'May 2006'	System	18 Aug 2020 17:58:26

**US3182292**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:01:25**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered '2006'	System	18 Aug 2020 17:58:26

US3182292

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:01:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Upper limb fracture, LLT: Arm fracture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 19:55:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 19:55:33
Data point term sent to Coder	System	18 Aug 2020 17:59:49
User entered 'Right arm fracture'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:58:49

US3182292

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:01:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered 'un May 2020'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:58:49

US3182292

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:01:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered '0'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:58:49

US3182292

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:01:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:40:17
DataPoint Un-verified.	Cassie Uminski (b) (4)	11 Sep 2020 18:32:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	11 Sep 2020 18:32:04
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:58:49

US3182292

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:01:25

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:40:19
User closed query 'Per DM CLR: Please consider adding stop date as MH #6 RIGHT ARM FRACTURE SURGICAL REPAIR on UN MAY 2020 is recorded. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 16:46:45
Query 'Per DM CLR: Please consider adding stop date as MH #6 RIGHT ARM FRACTURE SURGICAL REPAIR on UN MAY 2020 is recorded. Otherwise, provide clarification.' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:32:08
DataPoint Un-verified.	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:32:04
User entered 'un May 2020' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:32:04
User opened query 'Per DM CLR: Please consider adding stop date as MH #6 RIGHT ARM FRACTURE SURGICAL REPAIR on UN MAY 2020 is recorded. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 10:52:41
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered empty.	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:58:49



US3182292

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:01:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered '0'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:58:49

**US3182292**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:01:25**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered 'May 2020'	System	18 Aug 2020 17:58:49

**US3182292**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:01:25**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered '2020'	System	18 Aug 2020 17:58:49

**US3182292**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:01:25**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered 'May 2020'	System	11 Sep 2020 18:32:04
User entered empty.	System	18 Aug 2020 17:58:49

**US3182292**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:01:25**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered '2020'	System	11 Sep 2020 18:32:04
User entered empty.	System	18 Aug 2020 17:58:49

US3182292

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:01:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Fracture treatments (excl skull and spine), PT: Fracture treatment, LLT: Fracture repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 20:43:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 20:43:44
Data point term sent to Coder	System	18 Aug 2020 17:59:50
User entered 'Right arm fracture surgical repair'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:59:22

US3182292

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:01:25

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered 'un May 2020'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:59:22

US3182292

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:01:25

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered '0'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:59:22



US3182292

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:01:25

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:59:22

US3182292

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:01:25

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered 'un May 2020'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:59:22

US3182292

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:01:25

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:48:29
User entered '0'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:59:22

US3182292

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:01:25

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered 'May 2020'	System	18 Aug 2020 17:59:22

**US3182292**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:01:25**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered '2020'	System	18 Aug 2020 17:59:22

**US3182292**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:01:25**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered 'May 2020'	System	18 Aug 2020 17:59:22

**US3182292**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 22:01:25**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered '2020'	System	18 Aug 2020 17:59:22

US3182292

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:52:07
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:51:47



US3182292

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:52:07
User entered '11 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:51:47

US3182292

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:52:07
User entered '14:30'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:51:47

US3182292

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered '11 Aug 2020 14:30'	System	18 Aug 2020 17:51:47

US3182292

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:52:07
User entered '179.6' cm	Cassie Uminski (b) (4)	18 Aug 2020 17:51:47
DataPoint set to visible.	(b) (4) System	11 Aug 2020 19:35:32

US3182292

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:52:07
User entered '65.7' kg	Cassie Uminski (b) (4)	18 Aug 2020 17:51:47
DataPoint set to visible.	(b) (4) System	11 Aug 2020 19:35:32

US3182292

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
Amendment Manager: User entered '20.36820'	System	16 Sep 2020 23:52:14
User entered '20.4'	System	18 Aug 2020 17:51:47
DataPoint set to visible.	System	11 Aug 2020 19:35:32

US3182292

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered 'kg/m2'	System	18 Aug 2020 17:51:47
DataPoint set to visible.	System	11 Aug 2020 19:35:32

US3182292

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:52:07
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:51:47



US3182292

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 12:18:13
User closed query 'Per CDM: Since Temperature is ND, please consider to remove data recorded here. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 02:48:46
Query 'Per CDM: Since Temperature is ND, please consider to remove data recorded here. ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:30:13
DataPoint Un-verified.	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:30:07
User entered empty; reason for change Data Entry Error	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:30:07
User opened query 'Per CDM: Since Temperature is ND, please consider to remove data recorded here. ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 06:45:26
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:52:07
User entered 'Other (Other)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:51:47

US3182292

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 12:18:15
DataPoint Un-verified.	Cassie Uminski (b) (4)	11 Sep 2020 18:30:07
User entered empty; reason for change Data Entry Error	(b) (4) Cassie Uminski (b) (4)	11 Sep 2020 18:30:07
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:52:07
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:51:47

US3182292

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:52:07
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:51:47

US3182292

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered 'bpm'	System	18 Aug 2020 17:51:47

US3182292

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:52:07
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:51:47

US3182292

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered 'breaths/min'	System	18 Aug 2020 17:51:47

US3182292

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:52:07
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:51:47

**US3182292**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:01:25**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered 'mmHg'	System	18 Aug 2020 17:51:47



US3182292

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:52:07
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:51:47

US3182292

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User entered 'mmHg'	System	18 Aug 2020 17:51:47

US3182292

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59

US3182292

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59

US3182292

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:53:13
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:55:01

US3182292

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Sep 2020 14:38:39
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	11 Sep 2020 18:32:33
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 08:42:54
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	06 Sep 2020 16:17:23
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:53:13
User entered '11 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:55:01

US3182292

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:25

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:54:24
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:01

US3182292

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:25

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:54:24
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:01



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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:25

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:54:24
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:01

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:25

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:54:24
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:01

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:25

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:54:24
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:01

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:25

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:54:24
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:01

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:25

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:54:24
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:01

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:25

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:54:24
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:01

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:25

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:54:24
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:01

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:25

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:54:24
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:01



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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:25

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:54:24
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:01

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:25

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:54:24
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:01

US3182292

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:25

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:54:24
User entered (b) (6) employee'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:01

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:25

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
User entered '0'	Cassie Uminski (b) (4)	18 Aug 2020 17:57:01

US3182292

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:25

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:54:24
User entered '0'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:01

US3182292

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:25

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:54:24
User entered '0'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:01

US3182292

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:25

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:54:24
User entered '0'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:01

US3182292

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:25

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:54:24
User entered '0'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:01



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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:25

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:54:24
User entered 'I'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:01

US3182292

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:25

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
User entered '0'	Cassie Uminski (b) (4)	18 Aug 2020 17:57:01

US3182292

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:25

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:25:59
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:50:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:54:24
User entered empty.	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:57:01

US3182292

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:18
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:56:26

US3182292

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:18
User entered '11 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:56:26

US3182292

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:18
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:56:26

US3182292

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered 'VISIT1'	System	18 Aug 2020 17:56:26

US3182292

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:31
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 19:29:22



US3182292

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:01:25

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:31
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:39:41
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:39:41
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 19:29:22
User entered '103147' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 19:29:22

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:01:25

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:31
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 19:29:22

US3182292

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:01:25

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:31
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:46

US3182292

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:01:25

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:31
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:46

US3182292

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:01:25

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:31
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:46

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:01:25

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:31
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:46

US3182292

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:01:25

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:31
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:46

US3182292

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:01:25

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
Query 'Per CDM: This field requires a Yes or No response. Please complete.' canceled (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 20:07:15
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 20:10:52
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:17:52
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:35:14



US3182292

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:43
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:25

US3182292

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:25

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:43
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:25

US3182292

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:43
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:25

US3182292

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:25

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:43
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:25

US3182292

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:25

US3182292

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:43
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:43
User entered '11 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:25

US3182292

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:43
User entered '14:30'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:25



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered '11 Aug 2020 14:30'	System	18 Aug 2020 17:54:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:43
User entered '97.8' F	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:43
User entered 'Oral (Oral)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:43
User entered empty.	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:43
User entered '61'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered 'bpm'	System	18 Aug 2020 17:54:25

US3182292

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:43
User entered '12'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered 'breaths/min'	System	18 Aug 2020 17:54:25



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:43
User entered '110'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered 'mmHg'	System	18 Aug 2020 17:54:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:43
User entered '67'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered 'mmHg'	System	18 Aug 2020 17:54:25

US3182292

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:43
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:25

US3182292

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:25

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:43
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:25

US3182292

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:43
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:25



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:43
User entered '11 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:43
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 03:39:39
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		18 Aug 2020 17:54:25
User entered '16:17'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered '11 Aug 2020 16:17'	System	18 Aug 2020 17:54:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:43
User entered '97.1' F	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:43
User entered 'Oral (Oral)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:43
User entered empty.	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:43
User entered '51'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered 'bpm'	System	18 Aug 2020 17:54:25



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:43
User entered '14'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered 'breaths/min'	System	18 Aug 2020 17:54:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:43
User entered '107'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered 'mmHg'	System	18 Aug 2020 17:54:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:58:43
User entered '66'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:54:25

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered 'mmHg'	System	18 Aug 2020 17:54:25

US3182292

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:25
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:55:06

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:25
User entered empty.	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:55:06



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:38
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	11 Aug 2020 19:43:34

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:38
User entered empty.	Amy Maroun (b) (4) (b) (4)	11 Aug 2020 19:43:34

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:38
User entered empty.	Amy Maroun (b) (4) (b) (4)	11 Aug 2020 19:43:34

US3182292

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 19:43:34

US3182292

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:38
User entered '11 Aug 2020'	Amy Maroun (b) (4) (b) (4)	11 Aug 2020 19:43:34

US3182292

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:38
User entered '15:42'	Amy Maroun (b) (4) (b) (4)	11 Aug 2020 19:43:34

US3182292

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered '11 Aug 2020 15:42'	System	11 Aug 2020 19:43:34

US3182292

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:38
User entered 'Left Arm (LEFT ARM)'	Amy Maroun (b) (4) (b) (4)	11 Aug 2020 19:43:34



US3182292

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 16:00:38
User entered 'ONCE'	System	11 Aug 2020 19:43:34

US3182292

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 19:43:34

US3182292

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:56
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:56:12

US3182292

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:56
User entered '11 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:56:12

US3182292

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:00:56
User entered '15:20'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:56:12

US3182292

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered '11 Aug 2020 15:20'	System	18 Aug 2020 17:56:12

US3182292

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:01:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:01:19
User entered '11 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:55:38

US3182292

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:01:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:55:38



US3182292

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:01:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:01:19
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:55:38

US3182292

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:01:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:01:19
User entered '15:15'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:55:38

US3182292

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:01:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered '11 Aug 2020 15:15'	System	18 Aug 2020 17:55:38

US3182292

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:01:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cassie Uminski (b) (4)	18 Aug 2020 17:55:38
	(b) (4)	

US3182292

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:01:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:01:19
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:55:38

US3182292

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:01:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:01:19
User entered empty.	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:55:38

US3182292

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:01:25

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered empty.	System	18 Aug 2020 17:55:38

US3182292

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:01:34
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	18 Aug 2020 17:56:16



**US3182292**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:01:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered '1'	System	18 Aug 2020 17:56:16

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:01:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T16:09:25', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '65cefb66-304a-4931-8254-adda0de4ad0e' User entered 'Yes (Y)'	System	11 Aug 2020 20:10:37
	System	11 Aug 2020 20:10:37

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:01:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T16:10:22', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '65cefb66-304a-4931-8254-adda0de4ad0e' User entered '97.1'	System	11 Aug 2020 20:10:37
	System	11 Aug 2020 20:10:37

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T16:10:29', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '65cefb66-304a-4931-8254-adda0de4ad0e' User entered 'No (N)'	System	11 Aug 2020 20:10:37
	System	11 Aug 2020 20:10:37

**US3182292**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:01:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T16:10:33', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '65cefb66-304a-4931-8254-adda0de4ad0e' User entered '11 Aug 2020 16:10'	System	11 Aug 2020 20:10:37
	System	11 Aug 2020 20:10:37

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '11 Aug 2020 16:02'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '11 Aug 2020 18:32'	System	11 Aug 2020 19:43:34



US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:01:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T22:56:41', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '96106551-fea1-4d0e-9aa7-1c870687977e' User entered 'Yes (Y)'	System	12 Aug 2020 02:58:00
	System	12 Aug 2020 02:58:00

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:01:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T22:57:50', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '96106551-fea1-4d0e-9aa7-1c870687977e' User entered '97.9'	System	12 Aug 2020 02:58:00
	System	12 Aug 2020 02:58:00

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T22:57:53', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '96106551-fea1-4d0e-9aa7-1c870687977e' User entered 'No (N)'	System	12 Aug 2020 02:58:00
	System	12 Aug 2020 02:58:00

**US3182292**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:01:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T22:57:58', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '96106551-fea1-4d0e-9aa7-1c870687977e' User entered '11 Aug 2020 22:57'	System	12 Aug 2020 02:58:00
	System	12 Aug 2020 02:58:00

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '11 Aug 2020 19:27'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered 'Day 2'	System	11 Aug 2020 19:43:34



US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:01:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-12T13:19:04', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '01dc8e95-c34d-45ac-a023-c80b3449a35d' User entered 'Yes (Y)'	System	12 Aug 2020 17:20:24
	System	12 Aug 2020 17:20:24

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:01:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-12T13:20:11', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '01dc8e95-c34d-45ac-a023-c80b3449a35d' User entered '96.1'	System	12 Aug 2020 17:20:24
	System	12 Aug 2020 17:20:24

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-12T13:20:13', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '01dc8e95-c34d-45ac-a023-c80b3449a35d' User entered 'No (N)'	System	12 Aug 2020 17:20:24
	System	12 Aug 2020 17:20:24

**US3182292**

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

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:01:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-12T13:20:15', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '01dc8e95-c34d-45ac-a023-c80b3449a35d' User entered '12 Aug 2020 13:20'	System	12 Aug 2020 17:20:24
	System	12 Aug 2020 17:20:24

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered 'Day 3'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:01:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-13T17:58:24', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '15a69adb-ca7c-4b7c-9a2b-7a612425e6ec' User entered 'Yes (Y)'	System	13 Aug 2020 21:58:33
	System	13 Aug 2020 21:58:33



US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:01:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-13T17:58:27', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '15a69adb-ca7c-4b7c-9a2b-7a612425e6ec' User entered '95.9'	System	13 Aug 2020 21:58:33
	System	13 Aug 2020 21:58:33

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-13T17:58:29', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '15a69adb-ca7c-4b7c-9a2b-7a612425e6ec' User entered 'No (N)'	System	13 Aug 2020 21:58:33
	System	13 Aug 2020 21:58:33

**US3182292**

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

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

**Generated On: 11 Aug 2021 22:01:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-13T17:58:31', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '15a69adb-ca7c-4b7c-9a2b-7a612425e6ec' User entered '13 Aug 2020 17:58'	System	13 Aug 2020 21:58:33
	System	13 Aug 2020 21:58:33

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered 'Day 4'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:01:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-14T17:18:59', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '58ef5e04-a1a7-4e30-9110-06aa1a7c02ce' User entered 'Yes (Y)'	System	14 Aug 2020 21:19:50
	System	14 Aug 2020 21:19:50

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:01:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-14T17:19:08', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '58ef5e04-a1a7-4e30-9110-06aa1a7c02ce' User entered '97.6'	System	14 Aug 2020 21:19:50
	System	14 Aug 2020 21:19:50



US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-14T17:19:10', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '58ef5e04-a1a7-4e30-9110-06aa1a7c02ce'	System	14 Aug 2020 21:19:50
User entered 'No (N)'	System	14 Aug 2020 21:19:50

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:01:25

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-14T17:19:14', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '58ef5e04-a1a7-4e30-9110-06aa1a7c02ce' User entered '14 Aug 2020 17:19'	System	14 Aug 2020 21:19:50
	System	14 Aug 2020 21:19:50

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered 'Day 5'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:01:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-15T23:59:54', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '2bfca1ba-f9e1-416d-bf17-fd37b3f7994c' User entered 'Yes (Y)'	System	16 Aug 2020 04:00:08
	System	16 Aug 2020 04:00:08

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:01:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-15T23:59:57', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '2bfca1ba-f9e1-416d-bf17-fd37b3f7994c' User entered '96.9'	System	16 Aug 2020 04:00:08
	System	16 Aug 2020 04:00:08

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-15T23:59:59', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '2bfca1ba-f9e1-416d-bf17-fd37b3f7994c' User entered 'Yes (Y)'	System	16 Aug 2020 04:00:08
	System	16 Aug 2020 04:00:08



US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'this was an entry error by the subject. no meds taken ' (Site from System).	(b) (4), (b) (6)	17 Oct 2020 11:34:27
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Amy Maroun (b) (4)	11 Oct 2020 15:11:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T00:00:02', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '2bfca1ba-f9e1-416d-bf17-fd37b3f7994c'	(b) (4)	
User entered '1'	System	16 Aug 2020 04:00:08
	System	16 Aug 2020 04:00:08
	System	16 Aug 2020 04:00:08

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:01:25

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T00:00:02', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '2bfca1ba-f9e1-416d-bf17-fd37b3f7994c' User entered '0'	System	16 Aug 2020 04:00:08
	System	16 Aug 2020 04:00:08

**US3182292**

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

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:01:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T00:00:04', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '2bfca1ba-f9e1-416d-bf17-fd37b3f7994c' User entered '16 Aug 2020 00:00'	System	16 Aug 2020 04:00:08
	System	16 Aug 2020 04:00:08

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered 'Day 6'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:01:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T22:30:25', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'f85cbb38-c47e-4dde-abb1-1e0306b8d5e2'	System	17 Aug 2020 02:30:40
User entered 'Yes (Y)'	System	17 Aug 2020 02:30:40

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:01:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T22:30:30', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'f85cbb38-c47e-4dde-abb1-1e0306b8d5e2' User entered '97.4'	System	17 Aug 2020 02:30:40
	System	17 Aug 2020 02:30:40



US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T22:30:33', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'f85cbb38-c47e-4dde-abb1-1e0306b8d5e2'	System	17 Aug 2020 02:30:40
User entered 'No (N)'	System	17 Aug 2020 02:30:40

**US3182292**

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

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:01:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T22:30:35', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'f85cbb38-c47e-4dde-abb1-1e0306b8d5e2'	System	17 Aug 2020 02:30:40
User entered '16 Aug 2020 22:30'	System	17 Aug 2020 02:30:40

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered 'Day 7'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:01:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-17T17:45:24', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '997890d5-e282-4857-8519-548348f3f1ea' User entered 'Yes (Y)'	System	17 Aug 2020 21:45:33
	System	17 Aug 2020 21:45:33

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:01:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-17T17:45:27', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '997890d5-e282-4857-8519-548348f3f1ea' User entered '98.1'	System	17 Aug 2020 21:45:33
	System	17 Aug 2020 21:45:33

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-17T17:45:28', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '997890d5-e282-4857-8519-548348f3f1ea' User entered 'No (N)'	System	17 Aug 2020 21:45:33
	System	17 Aug 2020 21:45:33



**US3182292**

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

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:01:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-17T17:45:30', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '997890d5-e282-4857-8519-548348f3f1ea' User entered '17 Aug 2020 17:45'	System	17 Aug 2020 21:45:33
	System	17 Aug 2020 21:45:33

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:01:25

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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T16:10:58', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '0e841ee0-0125-4f0f-a61c-3a5e132c63e5'	System	11 Aug 2020 20:11:25
User entered 'None (1)'	System	11 Aug 2020 20:11:25

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:01:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T16:11:06', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '0e841ee0-0125-4f0f-a61c-3a5e132c63e5' User entered 'No (N)'	System	11 Aug 2020 20:11:25
	System	11 Aug 2020 20:11:25

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T16:11:10', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '0e841ee0-0125-4f0f-a61c-3a5e132c63e5' User entered 'No (N)'	System	11 Aug 2020 20:11:25
	System	11 Aug 2020 20:11:25

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:01:25

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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T16:11:18', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '0e841ee0-0125-4f0f-a61c-3a5e132c63e5'	System	11 Aug 2020 20:11:25
User entered 'None (1)'	System	11 Aug 2020 20:11:25



**US3182292**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:01:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T16:11:20', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '0e841ee0-0125-4f0f-a61c-3a5e132c63e5'	System	11 Aug 2020 20:11:25
User entered '11 Aug 2020 16:11'	System	11 Aug 2020 20:11:25

**US3182292**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:01:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '11 Aug 2020 16:02'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '11 Aug 2020 18:32'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:01:25

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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T22:58:17', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '97618a41-319c-4d92-ad5e-9239bb0e87d8'	System	12 Aug 2020 02:59:34
User entered 'None (1)'	System	12 Aug 2020 02:59:34

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:01:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T22:58:28', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '97618a41-319c-4d92-ad5e-9239bb0e87d8' User entered 'Yes (Y)'	System	12 Aug 2020 02:59:34
	System	12 Aug 2020 02:59:34

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:01:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T22:58:53', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '97618a41-319c-4d92-ad5e-9239bb0e87d8' User entered '5'	System	12 Aug 2020 02:59:34
	System	12 Aug 2020 02:59:34

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T22:58:57', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '97618a41-319c-4d92-ad5e-9239bb0e87d8' User entered 'No (N)'	System	12 Aug 2020 02:59:34
	System	12 Aug 2020 02:59:34



US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:01:25

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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T22:59:02', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '97618a41-319c-4d92-ad5e-9239bb0e87d8'	System	12 Aug 2020 02:59:34
User entered 'None (1)'	System	12 Aug 2020 02:59:34

**US3182292**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:01:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T22:59:31', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '97618a41-319c-4d92-ad5e-9239bb0e87d8'	System	12 Aug 2020 02:59:34
User entered '11 Aug 2020 22:59'	System	12 Aug 2020 02:59:34

**US3182292**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:01:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '11 Aug 2020 19:27'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered 'Day 2'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:01:25

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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-12T13:20:43', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'c605dda9-2e94-45d3-830f-4b8db4d5a167'	System	12 Aug 2020 17:21:00
User entered 'None (1)'	System	12 Aug 2020 17:21:00

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:01:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-12T13:20:49', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'c605dda9-2e94-45d3-830f-4b8db4d5a167'	System	12 Aug 2020 17:21:00
User entered 'Yes (Y)'	System	12 Aug 2020 17:21:00

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:01:25

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-12T13:20:51', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'c605dda9-2e94-45d3-830f-4b8db4d5a167' User entered '5'	System	12 Aug 2020 17:21:00
	System	12 Aug 2020 17:21:00



US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-12T13:20:53', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'c605dda9-2e94-45d3-830f-4b8db4d5a167' User entered 'No (N)'	System	12 Aug 2020 17:21:00
	System	12 Aug 2020 17:21:00

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:01:25

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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-12T13:20:55', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'c605dda9-2e94-45d3-830f-4b8db4d5a167' User entered 'None (1)'	System	12 Aug 2020 17:21:00
	System	12 Aug 2020 17:21:00

**US3182292**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:01:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-12T13:20:57', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'c605dda9-2e94-45d3-830f-4b8db4d5a167'	System	12 Aug 2020 17:21:00
User entered '12 Aug 2020 13:20'	System	12 Aug 2020 17:21:00

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered 'Day 3'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:01:25

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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-13T17:58:35', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '05579fed-a1cf-4666-9fc7-1dd30574490c'	System	13 Aug 2020 21:58:43
User entered 'None (1)'	System	13 Aug 2020 21:58:43

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:01:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-13T17:58:36', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '05579fed-a1cf-4666-9fc7-1dd30574490c' User entered 'No (N)'	System	13 Aug 2020 21:58:43
	System	13 Aug 2020 21:58:43



US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-13T17:58:38', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '05579fed-a1cf-4666-9fc7-1dd30574490c' User entered 'No (N)'	System	13 Aug 2020 21:58:43
	System	13 Aug 2020 21:58:43

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:01:25

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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-13T17:58:39', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '05579fed-a1cf-4666-9fc7-1dd30574490c'	System	13 Aug 2020 21:58:43
User entered 'None (1)'	System	13 Aug 2020 21:58:43

**US3182292**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:01:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-13T17:58:41', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '05579fed-a1cf-4666-9fc7-1dd30574490c' User entered '13 Aug 2020 17:58'	System	13 Aug 2020 21:58:43
	System	13 Aug 2020 21:58:43

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered 'Day 4'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:01:25

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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-14T17:18:18', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b044be0d-cafc-4fde-9a84-d192bc639efb' User entered 'None (1)'	System	14 Aug 2020 21:18:38
	System	14 Aug 2020 21:18:38

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:01:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-14T17:18:27', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b044be0d-cafc-4fde-9a84-d192bc639efb' User entered 'No (N)'	System	14 Aug 2020 21:18:38
	System	14 Aug 2020 21:18:38



US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-14T17:18:33', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b044be0d-cafc-4fde-9a84-d192bc639efb' User entered 'No (N)'	System	14 Aug 2020 21:18:38
	System	14 Aug 2020 21:18:38

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:01:25

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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-14T17:18:35', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b044be0d-cafc-4fde-9a84-d192bc639efb' User entered 'None (1)'	System	14 Aug 2020 21:18:38
	System	14 Aug 2020 21:18:38

**US3182292**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:01:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-14T17:18:37', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b044be0d-cafc-4fde-9a84-d192bc639efb' User entered '14 Aug 2020 17:18'	System	14 Aug 2020 21:18:38
	System	14 Aug 2020 21:18:38

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered 'Day 5'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:01:25

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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T00:00:06', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'fb1c2cef-6f07-4d81-8989-27a8c69512b8' User entered 'None (1)'	System	16 Aug 2020 04:00:16
	System	16 Aug 2020 04:00:16

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:01:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T00:00:08', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'fb1c2cef-6f07-4d81-8989-27a8c69512b8'	System	16 Aug 2020 04:00:16
User entered 'No (N)'	System	16 Aug 2020 04:00:16



US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T00:00:08', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'fb1c2cef-6f07-4d81-8989-27a8c69512b8' User entered 'No (N)'	System	16 Aug 2020 04:00:16
	System	16 Aug 2020 04:00:16

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:01:25

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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T00:00:09', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'fb1c2cef-6f07-4d81-8989-27a8c69512b8' User entered 'None (1)'	System	16 Aug 2020 04:00:16
	System	16 Aug 2020 04:00:16

**US3182292**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:01:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T00:00:11', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'fb1c2cef-6f07-4d81-8989-27a8c69512b8' User entered '16 Aug 2020 00:00'	System	16 Aug 2020 04:00:16
	System	16 Aug 2020 04:00:16

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered 'Day 6'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:01:25

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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T22:30:38', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '1e36089d-d117-4b07-a16d-f70c8ef109c0'	System	17 Aug 2020 02:30:46
User entered 'None (1)'	System	17 Aug 2020 02:30:46

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:01:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T22:30:39', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '1e36089d-d117-4b07-a16d-f70c8ef109c0' User entered 'No (N)'	System	17 Aug 2020 02:30:46
	System	17 Aug 2020 02:30:46



US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T22:30:39', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '1e36089d-d117-4b07-a16d-f70c8ef109c0' User entered 'No (N)'	System	17 Aug 2020 02:30:46
	System	17 Aug 2020 02:30:46

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:01:25

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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T22:30:40', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '1e36089d-d117-4b07-a16d-f70c8ef109c0' User entered 'None (1)'	System	17 Aug 2020 02:30:46
	System	17 Aug 2020 02:30:46

**US3182292**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:01:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T22:30:42', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '1e36089d-d117-4b07-a16d-f70c8ef109c0' User entered '16 Aug 2020 22:30'	System	17 Aug 2020 02:30:46
	System	17 Aug 2020 02:30:46

**US3182292**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:01:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:43:34

**US3182292**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:01:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered 'Day 7'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:01:25

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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-17T17:45:33', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '84a68539-402d-4551-814a-97e9de543f87'	System	17 Aug 2020 21:45:54
User entered 'None (1)'	System	17 Aug 2020 21:45:54

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:01:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-17T17:45:44', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '84a68539-402d-4551-814a-97e9de543f87'	System	17 Aug 2020 21:45:54
User entered 'No (N)'	System	17 Aug 2020 21:45:54



US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-17T17:45:45', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '84a68539-402d-4551-814a-97e9de543f87'	System	17 Aug 2020 21:45:54
User entered 'No (N)'	System	17 Aug 2020 21:45:54

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:01:25

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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-17T17:45:51', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '84a68539-402d-4551-814a-97e9de543f87'	System	17 Aug 2020 21:45:54
User entered 'None (1)'	System	17 Aug 2020 21:45:54

**US3182292**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:01:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-17T17:45:52', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '84a68539-402d-4551-814a-97e9de543f87' User entered '17 Aug 2020 17:45'	System	17 Aug 2020 21:45:54
	System	17 Aug 2020 21:45:54

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:43:34

**US3182292**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:01:25**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T16:11:27', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'cb79b968-d344-4a13-b55f-46367b8ecdd5' User entered 'None (0)'	System	11 Aug 2020 20:11:53
	System	11 Aug 2020 20:11:53

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:01:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T16:11:31', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'cb79b968-d344-4a13-b55f-46367b8ecdd5' User entered 'None (0)'	System	11 Aug 2020 20:11:53
	System	11 Aug 2020 20:11:53



US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:01:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T16:11:34', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'cb79b968-d344-4a13-b55f-46367b8ecdd5' User entered 'None (0)'	System	11 Aug 2020 20:11:53
	System	11 Aug 2020 20:11:53

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:01:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T16:11:36', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'cb79b968-d344-4a13-b55f-46367b8ecdd5' User entered 'None (0)'	System	11 Aug 2020 20:11:53
	System	11 Aug 2020 20:11:53

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:01:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T16:11:39', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'cb79b968-d344-4a13-b55f-46367b8ecdd5' User entered 'None (0)'	System	11 Aug 2020 20:11:53
	System	11 Aug 2020 20:11:53

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:01:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T16:11:41', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'cb79b968-d344-4a13-b55f-46367b8ecdd5' User entered 'None (0)'	System	11 Aug 2020 20:11:53
	System	11 Aug 2020 20:11:53

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:01:25

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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T16:11:47', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'cb79b968-d344-4a13-b55f-46367b8ecdd5'	System	11 Aug 2020 20:11:53
User entered 'No (N)'	System	11 Aug 2020 20:11:53

**US3182292**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:01:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T16:11:50', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'cb79b968-d344-4a13-b55f-46367b8ecdd5' User entered '11 Aug 2020 16:11'	System	11 Aug 2020 20:11:53
	System	11 Aug 2020 20:11:53

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '11 Aug 2020 16:02'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '11 Aug 2020 18:32'	System	11 Aug 2020 19:43:34



US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:01:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T22:59:34', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '7b2693a0-421c-4513-a8e8-955366cc8ed0' User entered 'None (0)'	System	12 Aug 2020 03:00:03
	System	12 Aug 2020 03:00:03

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:01:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T22:59:44', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '7b2693a0-421c-4513-a8e8-955366cc8ed0' User entered 'None (0)'	System	12 Aug 2020 03:00:03
	System	12 Aug 2020 03:00:03

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:01:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T22:59:46', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '7b2693a0-421c-4513-a8e8-955366cc8ed0' User entered 'None (0)'	System	12 Aug 2020 03:00:03
	System	12 Aug 2020 03:00:03

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:01:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T22:59:48', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '7b2693a0-421c-4513-a8e8-955366cc8ed0' User entered 'None (0)'	System	12 Aug 2020 03:00:03
	System	12 Aug 2020 03:00:03

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:01:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T22:59:49', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '7b2693a0-421c-4513-a8e8-955366cc8ed0' User entered 'None (0)'	System	12 Aug 2020 03:00:03
	System	12 Aug 2020 03:00:03

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:01:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T22:59:50', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '7b2693a0-421c-4513-a8e8-955366cc8ed0' User entered 'None (0)'	System	12 Aug 2020 03:00:03
	System	12 Aug 2020 03:00:03

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:01:25

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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T22:59:56', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '7b2693a0-421c-4513-a8e8-955366cc8ed0' User entered 'No (N)'	System	12 Aug 2020 03:00:03
	System	12 Aug 2020 03:00:03



**US3182292**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:01:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-11T22:59:58', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '7b2693a0-421c-4513-a8e8-955366cc8ed0' User entered '11 Aug 2020 22:59'	System	12 Aug 2020 03:00:03
	System	12 Aug 2020 03:00:03

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '11 Aug 2020 19:27'	System	11 Aug 2020 19:43:34

**US3182292**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:01:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered 'Day 2'	System	11 Aug 2020 19:43:34

**US3182292**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:01:25**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-12T13:20:59', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '7ec34b93-e8d4-453d-af6d-c7ec4f8a8338' User entered 'None (0)'	System	12 Aug 2020 17:21:12
	System	12 Aug 2020 17:21:12

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:01:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-12T13:21:01', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '7ec34b93-e8d4-453d-af6d-c7ec4f8a8338' User entered 'None (0)'	System	12 Aug 2020 17:21:12
	System	12 Aug 2020 17:21:12

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:01:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-12T13:21:02', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '7ec34b93-e8d4-453d-af6d-c7ec4f8a8338' User entered 'None (0)'	System	12 Aug 2020 17:21:12
	System	12 Aug 2020 17:21:12

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:01:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-12T13:21:03', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '7ec34b93-e8d4-453d-af6d-c7ec4f8a8338' User entered 'None (0)'	System	12 Aug 2020 17:21:12
	System	12 Aug 2020 17:21:12



US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:01:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-12T13:21:04', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '7ec34b93-e8d4-453d-af6d-c7ec4f8a8338' User entered 'None (0)'	System	12 Aug 2020 17:21:12
	System	12 Aug 2020 17:21:12

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:01:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-12T13:21:05', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '7ec34b93-e8d4-453d-af6d-c7ec4f8a8338' User entered 'None (0)'	System	12 Aug 2020 17:21:12
	System	12 Aug 2020 17:21:12

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:01:25

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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-12T13:21:07', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '7ec34b93-e8d4-453d-af6d-c7ec4f8a8338'	System	12 Aug 2020 17:21:12
User entered 'No (N)'	System	12 Aug 2020 17:21:12

**US3182292**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:01:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-12T13:21:08', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '7ec34b93-e8d4-453d-af6d-c7ec4f8a8338'	System	12 Aug 2020 17:21:12
User entered '12 Aug 2020 13:21'	System	12 Aug 2020 17:21:12

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered 'Day 3'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:01:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-13T17:58:44', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b4177d4d-7c1a-40ba-a7cf-d49bee5105b3' User entered 'None (0)'	System	13 Aug 2020 21:58:55
	System	13 Aug 2020 21:58:55



US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:01:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-13T17:58:45', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b4177d4d-7c1a-40ba-a7cf-d49bee5105b3' User entered 'None (0)'	System	13 Aug 2020 21:58:55
	System	13 Aug 2020 21:58:55

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:01:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-13T17:58:46', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b4177d4d-7c1a-40ba-a7cf-d49bee5105b3' User entered 'None (0)'	System	13 Aug 2020 21:58:55
	System	13 Aug 2020 21:58:55

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:01:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-13T17:58:47', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b4177d4d-7c1a-40ba-a7cf-d49bee5105b3' User entered 'None (0)'	System	13 Aug 2020 21:58:55
	System	13 Aug 2020 21:58:55

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:01:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-13T17:58:48', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b4177d4d-7c1a-40ba-a7cf-d49bee5105b3' User entered 'None (0)'	System	13 Aug 2020 21:58:55
	System	13 Aug 2020 21:58:55

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:01:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-13T17:58:49', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b4177d4d-7c1a-40ba-a7cf-d49bee5105b3' User entered 'None (0)'	System	13 Aug 2020 21:58:55
	System	13 Aug 2020 21:58:55

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:01:25

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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-13T17:58:51', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b4177d4d-7c1a-40ba-a7cf-d49bee5105b3' User entered 'No (N)'	System	13 Aug 2020 21:58:55
	System	13 Aug 2020 21:58:55

**US3182292**

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

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

**Generated On: 11 Aug 2021 22:01:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-13T17:58:53', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b4177d4d-7c1a-40ba-a7cf-d49bee5105b3' User entered '13 Aug 2020 17:58'	System	13 Aug 2020 21:58:55
	System	13 Aug 2020 21:58:55

**US3182292**

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

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

**Generated On: 11 Aug 2021 22:01:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:43:34



**US3182292**

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

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

**Generated On: 11 Aug 2021 22:01:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered 'Day 4'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:01:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-14T17:18:40', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '9ae16681-e756-43c9-9060-84cafbac04f1' User entered 'None (0)'	System	14 Aug 2020 21:18:53
	System	14 Aug 2020 21:18:53

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:01:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-14T17:18:42', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '9ae16681-e756-43c9-9060-84cafbac04f1' User entered 'None (0)'	System	14 Aug 2020 21:18:53
	System	14 Aug 2020 21:18:53

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:01:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-14T17:18:44', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '9ae16681-e756-43c9-9060-84cafbac04f1' User entered 'None (0)'	System	14 Aug 2020 21:18:53
	System	14 Aug 2020 21:18:53

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:01:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-14T17:18:45', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '9ae16681-e756-43c9-9060-84cafbac04f1' User entered 'None (0)'	System	14 Aug 2020 21:18:53
	System	14 Aug 2020 21:18:53

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:01:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-14T17:18:46', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '9ae16681-e756-43c9-9060-84cafbac04f1' User entered 'None (0)'	System	14 Aug 2020 21:18:53
	System	14 Aug 2020 21:18:53

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:01:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-14T17:18:47', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '9ae16681-e756-43c9-9060-84cafbac04f1' User entered 'None (0)'	System	14 Aug 2020 21:18:53
	System	14 Aug 2020 21:18:53



US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:01:25

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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-14T17:18:49', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '9ae16681-e756-43c9-9060-84cafbac04f1' User entered 'No (N)'	System	14 Aug 2020 21:18:53
	System	14 Aug 2020 21:18:53

**US3182292**

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

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

**Generated On: 11 Aug 2021 22:01:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-14T17:18:52', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '9ae16681-e756-43c9-9060-84cafbac04f1' User entered '14 Aug 2020 17:18'	System	14 Aug 2020 21:18:53
	System	14 Aug 2020 21:18:53

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered 'Day 5'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:01:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T00:00:13', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '8287d028-5311-48a3-a637-29360828fbc1' User entered 'None (0)'	System	16 Aug 2020 04:00:24
	System	16 Aug 2020 04:00:24

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:01:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T00:00:15', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '8287d028-5311-48a3-a637-29360828fbe1' User entered 'None (0)'	System	16 Aug 2020 04:00:24
	System	16 Aug 2020 04:00:24

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:01:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T00:00:16', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '8287d028-5311-48a3-a637-29360828fbe1' User entered 'None (0)'	System	16 Aug 2020 04:00:24
	System	16 Aug 2020 04:00:24



US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:01:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T00:00:16', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '8287d028-5311-48a3-a637-29360828fbe1' User entered 'None (0)'	System	16 Aug 2020 04:00:24
	System	16 Aug 2020 04:00:24

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:01:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T00:00:17', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '8287d028-5311-48a3-a637-29360828fbe1' User entered 'None (0)'	System	16 Aug 2020 04:00:24
	System	16 Aug 2020 04:00:24

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:01:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T00:00:18', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '8287d028-5311-48a3-a637-29360828fbe1' User entered 'None (0)'	System	16 Aug 2020 04:00:24
	System	16 Aug 2020 04:00:24

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:01:25

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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T00:00:19', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '8287d028-5311-48a3-a637-29360828fbe1' User entered 'No (N)'	System	16 Aug 2020 04:00:24
	System	16 Aug 2020 04:00:24

**US3182292**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:01:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T00:00:20', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '8287d028-5311-48a3-a637-29360828fbe1' User entered '16 Aug 2020 00:00'	System	16 Aug 2020 04:00:24
	System	16 Aug 2020 04:00:24

**US3182292**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:01:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:43:34

**US3182292**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:01:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered 'Day 6'	System	11 Aug 2020 19:43:34



**US3182292**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:01:25**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T22:30:44', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'a58885e2-c3ca-4d2c-87d3-9b2b85995209' User entered 'None (0)'	System	17 Aug 2020 02:30:52
	System	17 Aug 2020 02:30:52

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:01:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T22:30:45', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'a58885e2-c3ca-4d2c-87d3-9b2b85995209' User entered 'None (0)'	System	17 Aug 2020 02:30:52
	System	17 Aug 2020 02:30:52

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:01:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T22:30:45', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'a58885e2-c3ca-4d2c-87d3-9b2b85995209' User entered 'None (0)'	System	17 Aug 2020 02:30:52
	System	17 Aug 2020 02:30:52

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:01:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T22:30:46', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'a58885e2-c3ca-4d2c-87d3-9b2b85995209' User entered 'None (0)'	System	17 Aug 2020 02:30:52
	System	17 Aug 2020 02:30:52

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:01:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T22:30:47', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'a58885e2-c3ca-4d2c-87d3-9b2b85995209' User entered 'None (0)'	System	17 Aug 2020 02:30:52
	System	17 Aug 2020 02:30:52

**US3182292**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:01:25**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T22:30:47', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'a58885e2-c3ca-4d2c-87d3-9b2b85995209' User entered 'None (0)'	System	17 Aug 2020 02:30:52
	System	17 Aug 2020 02:30:52

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:01:25

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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T22:30:48', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'a58885e2-c3ca-4d2c-87d3-9b2b85995209' User entered 'No (N)'	System	17 Aug 2020 02:30:52
	System	17 Aug 2020 02:30:52

**US3182292**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:01:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-16T22:30:50', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'a58885e2-c3ca-4d2c-87d3-9b2b85995209' User entered '16 Aug 2020 22:30'	System	17 Aug 2020 02:30:52
	System	17 Aug 2020 02:30:52



**US3182292**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:01:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:43:34

**US3182292**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:01:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered 'Day 7'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:01:25

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-17T17:45:55', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b8971b8e-40c4-4afd-b1f3-e55dfe29440a' User entered 'None (0)'	System	17 Aug 2020 21:46:11
	System	17 Aug 2020 21:46:11

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:01:25

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-17T17:45:56', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b8971b8e-40c4-4afd-b1f3-e55dfe29440a' User entered 'None (0)'	System	17 Aug 2020 21:46:11
	System	17 Aug 2020 21:46:11

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:01:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-17T17:45:57', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b8971b8e-40c4-4afd-b1f3-e55dfe29440a' User entered 'None (0)'	System	17 Aug 2020 21:46:11
	System	17 Aug 2020 21:46:11

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:01:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-17T17:45:58', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b8971b8e-40c4-4afd-b1f3-e55dfe29440a' User entered 'None (0)'	System	17 Aug 2020 21:46:11
	System	17 Aug 2020 21:46:11

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:01:25

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-17T17:45:59', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b8971b8e-40c4-4afd-b1f3-e55dfe29440a' User entered 'None (0)'	System	17 Aug 2020 21:46:11
	System	17 Aug 2020 21:46:11



US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:01:25

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-17T17:46:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b8971b8e-40c4-4afd-b1f3-e55dfe29440a' User entered 'None (0)'	System	17 Aug 2020 21:46:11
	System	17 Aug 2020 21:46:11

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:01:25

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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-17T17:46:01', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b8971b8e-40c4-4afd-b1f3-e55dfe29440a' User entered 'No (N)'	System	17 Aug 2020 21:46:11
	System	17 Aug 2020 21:46:11

**US3182292**

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

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:01:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-08-17T17:46:07', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b8971b8e-40c4-4afd-b1f3-e55dfe29440a' User entered '17 Aug 2020 17:46'	System	17 Aug 2020 21:46:11
	System	17 Aug 2020 21:46:11

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:01:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:43:34

US3182292

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:01:25

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:43:34

US3182292

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:01:52
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	21 Aug 2020 18:01:42

US3182292

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:01:52
User entered '18 Aug 2020'	Alec Ireland (b) (4) (b) (4)	21 Aug 2020 18:01:42

US3182292

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:01:52
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4) (b) (4)	21 Aug 2020 18:01:42



US3182292

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:01:52
User entered empty.	Alec Ireland (b) (4) (b) (4)	21 Aug 2020 18:01:42

US3182292

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:01:58
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	21 Aug 2020 18:01:35

US3182292

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered 'I'	System	21 Aug 2020 18:01:35

US3182292

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:35:45
User closed query 'Please add the COVID Impact form. Instructions are on page 32 of the eCRF completion guidelines.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:33:47
Query 'Please add the COVID Impact form. Instructions are on page 32 of the eCRF completion guidelines.' answered with 'Please advise as day 15 is not provided in the dropdown on the COVID impact crf' (Site from CRA).	Cassie Uminski (b) (4) (b) (4)	07 Dec 2020 19:20:25
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:08:29
User opened query 'Please add the COVID Impact form. Instructions are on page 32 of the eCRF completion guidelines.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 17:06:48
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	11 Nov 2020 16:22:40
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	11 Nov 2020 16:22:36
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	11 Nov 2020 16:22:36
User entered 'No (N)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	11 Nov 2020 16:22:36
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	11 Nov 2020 16:22:21

US3182292

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	11 Nov 2020 16:22:21
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	11 Nov 2020 16:22:21
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	11 Nov 2020 16:22:09
User entered 'No (N)'	Cassie Uminski (b) (4)	11 Nov 2020 16:19:30

US3182292

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:08:29
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Nov 2020 16:19:30

US3182292

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:08:29
User entered empty; reason for change Data Entry Error	Cassie Uminski (b) (4)	11 Nov 2020 16:22:40
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	11 Nov 2020 16:22:09
User entered empty.	Cassie Uminski (b) (4)	11 Nov 2020 16:19:30

US3182292

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:08:29
User entered 'Subject was under COVD surveillance and receiving daily telemedicine calls during this time frame.'	Cassie Uminski (b) (4) (b) (4)	11 Nov 2020 16:19:30



US3182292

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:55:35
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	10 Sep 2020 18:09:10

**US3182292**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:01:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered 'I'	System	10 Sep 2020 18:09:10

US3182292

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:56:05
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	10 Sep 2020 18:09:20

US3182292

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:56:05
User entered '2 Sep 2020'	Alec Ireland (b) (4) (b) (4)	10 Sep 2020 18:09:20

US3182292

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:56:05
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4) (b) (4)	10 Sep 2020 18:09:20

US3182292

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:56:05
User entered empty.	Alec Ireland (b) (4) (b) (4)	10 Sep 2020 18:09:20

US3182292

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:56:10
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	10 Sep 2020 18:09:25

**US3182292**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:01:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered 'I'	System	10 Sep 2020 18:09:25



US3182292

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:13
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:32:33

US3182292

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:13
User entered '10 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:32:33

US3182292

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:13
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:32:33

US3182292

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered 'VISIT2'	System	11 Sep 2020 18:32:33

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4)	11 Sep 2020 18:32:58
	(b) (4)	

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:47
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:32:58

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:47
User entered '10 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:32:58

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:47
User entered '11:47'	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:32:58



US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered '10 Sep 2020 11:47'	System	11 Sep 2020 18:32:58

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:47
User entered '98.1' F	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:32:58

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:47
User entered 'Oral (Oral)'	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:32:58

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:47
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:32:58

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:47
User entered '47'	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:32:58

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered 'bpm'	System	11 Sep 2020 18:32:58

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:47
User entered '16'	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:32:58

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered 'breaths/min'	System	11 Sep 2020 18:32:58



US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:47
User entered '99'	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:32:58

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered 'mmHg'	System	11 Sep 2020 18:32:58

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:47
User entered '61'	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:32:58

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered 'mmHg'	System	11 Sep 2020 18:32:58

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:32:58

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:47
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:32:58

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:47
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:32:58

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:47
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:32:58



US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered empty.	System	11 Sep 2020 18:32:58

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:47
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:32:58

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:47
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:32:58

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:47
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:32:58

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:47
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:32:58

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered empty.	System	11 Sep 2020 18:32:58

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:47
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:32:58

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered empty.	System	11 Sep 2020 18:32:58



US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:47
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:32:58

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered empty.	System	11 Sep 2020 18:32:58

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:47
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:32:58

US3182292

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered empty.	System	11 Sep 2020 18:32:58

US3182292

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:55
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:33:30

US3182292

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:58:55
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:33:30

US3182292

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:59:30
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:34:19

US3182292

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:59:30
Query 'Per CDM: Response Noted. Per CCGs page -30, any confirmed SARS-CoV-2 infection or COVID-19 should be recorded as an MAAE .Please update an AE form accordingly. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 04:01:48
User opened query 'Per CDM: Response Noted. Per CCGs page -30, any confirmed SARS-CoV-2 infection or COVID-19 should be recorded as an MAAE .Please update an AE form accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 02:32:48
User entered 'Confirmed COVID-19 (COVID)'	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:34:19



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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:59:30
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:34:19

US3182292

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered empty.	System	11 Sep 2020 18:34:19

US3182292

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:59:30
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:34:19

US3182292

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:59:30
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:34:19

US3182292

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered empty.	System	11 Sep 2020 18:34:19

US3182292

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:59:30
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:34:19

US3182292

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:59:30
User entered empty.	System	11 Sep 2020 18:34:19

US3182292

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered empty.	System	11 Sep 2020 18:34:19



US3182292

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:59:43
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:33:54

US3182292

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:59:43
User entered '10 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:33:54

US3182292

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:59:43
User entered '12:00'	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:33:54

US3182292

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered '10 Sep 2020 12:00'	System	11 Sep 2020 18:33:54

US3182292

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:01:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:59:54
User entered '10 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:33:42

US3182292

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:01:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:33:42

US3182292

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:01:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:59:54
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:33:42

US3182292

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:01:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:59:54
User entered '11:42'	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:33:42



**US3182292**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:01:25**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered '10 Sep 2020 11:42'	System	11 Sep 2020 18:33:42

US3182292

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:01:25

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:33:42

US3182292

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:01:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:59:54
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:33:42

US3182292

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:01:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:59:54
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:33:42

US3182292

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:01:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered empty.	System	11 Sep 2020 18:33:42

US3182292

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:00:00
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	11 Sep 2020 18:34:25

**US3182292**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:01:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered '1'	System	11 Sep 2020 18:34:25

US3182292

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:56:30
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 15:04:42



US3182292

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:56:30
User entered '17 Sep 2020'	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 15:04:42

US3182292

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:56:30
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 15:04:42

US3182292

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:56:30
User entered empty.	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 15:04:42

US3182292

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	19 Feb 2021 18:35:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:56:37
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 15:04:32

US3182292

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered 'I'	System	24 Sep 2020 15:04:32

US3182292

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:56:53
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 18:46:00

US3182292

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:56:53
User entered '24 Sep 2020'	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 18:46:00

US3182292

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:56:53
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 18:46:00



US3182292

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:56:53
User entered empty.	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 18:46:00

US3182292

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:56:58
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	24 Sep 2020 18:45:52

**US3182292**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:01:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered 'I'	System	24 Sep 2020 18:45:52

US3182292

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:57:11
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	02 Oct 2020 18:51:29

US3182292

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:57:11
User entered '1 Oct 2020'	Alec Ireland (b) (4) (b) (4)	02 Oct 2020 18:51:29

US3182292

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:57:11
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4) (b) (4)	02 Oct 2020 18:51:29

US3182292

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:57:11
User entered empty.	Alec Ireland (b) (4) (b) (4)	02 Oct 2020 18:51:29

US3182292

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:57:16
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	02 Oct 2020 18:51:22



**US3182292**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:01:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered 'I'	System	02 Oct 2020 18:51:22

US3182292

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:00:24
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 15:02:05

US3182292

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:00:24
User entered '8 Oct 2020'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 15:02:05

US3182292

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:00:24
User entered 'Clinic (Clinic)'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 15:02:05

**US3182292**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:01:25**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered 'VISIT3'	System	11 Oct 2020 15:02:05

US3182292

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:00:39
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 15:02:49

US3182292

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:00:39
User entered '8 Oct 2020'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 15:02:49

US3182292

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:00:39
User entered '11:15'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 15:02:49



**US3182292**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:01:25**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered '8 Oct 2020 11:15'	System	11 Oct 2020 15:02:49

US3182292

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:00:39
User entered '98.0' F	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 15:02:49

US3182292

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:00:39
User entered 'Oral (Oral)'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 15:02:49

US3182292

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:00:39
User entered empty.	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 15:02:49

US3182292

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:00:39
User entered '72'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 15:02:49

**US3182292**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:01:25**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered 'bpm'	System	11 Oct 2020 15:02:49

US3182292

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:00:39
User entered '14'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 15:02:49

US3182292

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered 'breaths/min'	System	11 Oct 2020 15:02:49



US3182292

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:00:39
User entered '103'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 15:02:49

US3182292

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered 'mmHg'	System	11 Oct 2020 15:02:49

US3182292

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:00:39
User entered '67'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 15:02:49

US3182292

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered 'mmHg'	System	11 Oct 2020 15:02:49

US3182292

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26

US3182292

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26

US3182292

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:00:48
User entered 'No (N)'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 15:02:59

US3182292

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:00:48
User entered empty.	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 15:02:59



US3182292

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:00:56
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 15:03:23

US3182292

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:00:56
User entered '8 Oct 2020'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 15:03:23

US3182292

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:00:56
User entered '11:23'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 15:03:23

US3182292

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered '8 Oct 2020 11:23'	System	11 Oct 2020 15:03:23

US3182292

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:24:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:01:01
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 15:03:29

**US3182292**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:01:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered '1'	System	11 Oct 2020 15:03:29

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered 'Day 64'	System	11 Aug 2020 19:43:34

US3182292

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

[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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-10-14T18:16:48', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b2dbd6dc-c45e-44e7-99fa-7fc8fdb23ea3' User entered 'No (N)'	System	14 Oct 2020 22:16:56
	System	14 Oct 2020 22:16:56



US3182292

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

Have you been exposed to someone with 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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-10-14T18:16:51', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b2dbd6dc-c45e-44e7-99fa-7fc8fdb23ea3'	System	14 Oct 2020 22:16:56
User entered 'No (N)'	System	14 Oct 2020 22:16:56

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-10-14T18:16:53', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b2dbd6dc-c45e-44e7-99fa-7fc8fdb23ea3' User entered '14 Oct 2020 18:16:53'	System	14 Oct 2020 22:16:56
	System	14 Oct 2020 22:16:56

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 19:43:34

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 19:43:34

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered 'Day 71'	System	11 Aug 2020 19:43:34

US3182292

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

[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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-10-18T03:57:16', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'fefe7794-3039-43d2-9f0b-d4022345fceb' User entered 'No (N)'	System	18 Oct 2020 07:57:23
	System	18 Oct 2020 07:57:23

US3182292

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

Have you been exposed to someone with 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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-10-18T03:57:17', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'fefe7794-3039-43d2-9f0b-d4022345fceb'	System	18 Oct 2020 07:57:23
User entered 'No (N)'	System	18 Oct 2020 07:57:23

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-10-18T03:57:20', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'fefe7794-3039-43d2-9f0b-d4022345fceb' User entered '18 Oct 2020 03:57:20'	System	18 Oct 2020 07:57:23
	System	18 Oct 2020 07:57:23



**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 19:43:34

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 19:43:34

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered 'Day 78'	System	11 Aug 2020 19:43:34

US3182292

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

[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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-10-25T00:01:38', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'e4b22127-8cf0-40a7-bac4-ad7e7e327780' User entered 'No (N)'	System	25 Oct 2020 04:01:49
	System	25 Oct 2020 04:01:49

US3182292

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

Have you been exposed to someone with 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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-10-25T00:01:40', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'e4b22127-8cf0-40a7-bac4-ad7e7e327780'	System	25 Oct 2020 04:01:49
User entered 'No (N)'	System	25 Oct 2020 04:01:49

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-10-25T00:01:42', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'e4b22127-8cf0-40a7-bac4-ad7e7e327780' User entered '25 Oct 2020 00:01:42'	System	25 Oct 2020 04:01:49
	System	25 Oct 2020 04:01:49

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 19:43:34

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 19:43:34



**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered 'Day 92'	System	11 Aug 2020 19:43:34

US3182292

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

[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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-11-11T17:59:33', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '96aff74b-0ced-4101-bcbc-70dd42b1e588'	System	11 Nov 2020 22:59:43
User entered 'No (N)'	System	11 Nov 2020 22:59:43

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Have you been exposed to someone with 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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-11-11T17:59:35', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '96aff74b-0ced-4101-bcbc-70dd42b1e588'	System	11 Nov 2020 22:59:43
User entered 'No (N)'	System	11 Nov 2020 22:59:43

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-11-11T17:59:38', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '96aff74b-0ced-4101-bcbc-70dd42b1e588' User entered '11 Nov 2020 17:59:38'	System	11 Nov 2020 22:59:43
	System	11 Nov 2020 22:59:43

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 19:43:34

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 19:43:34

US3182292

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered 'Day 99'	System	11 Aug 2020 19:43:34

US3182292

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:25

[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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-11-15T00:16:15', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '306ff1ee-576f-4fd1-8088-838e78b10e3b' User entered 'No (N)'	System	15 Nov 2020 05:16:23
	System	15 Nov 2020 05:16:23



**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Have you been exposed to someone with 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 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-11-15T00:16:17', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '306ff1ee-576f-4fd1-8088-838e78b10e3b'	System	15 Nov 2020 05:16:23
User entered 'No (N)'	System	15 Nov 2020 05:16:23

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-11-15T00:16:19', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '306ff1ee-576f-4fd1-8088-838e78b10e3b' User entered '15 Nov 2020 00:16:19'	System	15 Nov 2020 05:16:23
	System	15 Nov 2020 05:16:23

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 19:43:34

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:36:49
Data entry locked.	System	11 Aug 2020 19:43:34
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 19:43:34

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 04:07:45



**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-11-29T00:04:36', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '6277fbc2-1444-4a7d-8489-a41771acc7fb' User entered 'No (N)'	System	29 Nov 2020 05:04:44

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Have you been exposed to someone with 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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-11-29T00:04:37', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '6277fbc2-1444-4a7d-8489-a41771acc7fb' User entered 'No (N)'	System	29 Nov 2020 05:04:44

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-11-29T00:04:39', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '6277fbc2-1444-4a7d-8489-a41771acc7fb' User entered '29 Nov 2020 00:04:39'	System	29 Nov 2020 05:04:44
	System	29 Nov 2020 05:04:44

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-12-05T12:00:34', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'bec91782-261a-475a-8c26-f0e93fcbc2b4'	System	05 Dec 2020 17:00:42
User entered 'No (N)'	System	05 Dec 2020 17:00:42

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Have you been exposed to someone with 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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-12-05T12:00:35', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'bec91782-261a-475a-8c26-f0e93fcbc2b4'	System	05 Dec 2020 17:00:42
User entered 'No (N)'	System	05 Dec 2020 17:00:42



**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-12-05T12:00:37', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'bec91782-261a-475a-8c26-f0e93fcbc2b4' User entered '05 Dec 2020 12:00:37'	System	05 Dec 2020 17:00:42
	System	05 Dec 2020 17:00:42

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-12-10T00:45:44', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b1c3f3d2-1ebb-4334-8de1-236bc9bb0571' User entered 'No (N)'	System	10 Dec 2020 05:45:49
	System	10 Dec 2020 05:45:49

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

Have you been exposed to someone with 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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-12-10T00:45:45', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b1c3f3d2-1ebb-4334-8de1-236bc9bb0571'	System	10 Dec 2020 05:45:49
User entered 'No (N)'	System	10 Dec 2020 05:45:49

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-12-10T00:45:47', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b1c3f3d2-1ebb-4334-8de1-236bc9bb0571' User entered '10 Dec 2020 00:45:47'	System	10 Dec 2020 05:45:49
	System	10 Dec 2020 05:45:49

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 04:07:45



**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-12-17T00:05:53', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '54660855-50d3-4f8a-a81d-b7bba6f91ab2' User entered 'No (N)'	System	17 Dec 2020 05:05:59
	System	17 Dec 2020 05:05:59

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Have you been exposed to someone with 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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-12-17T00:05:54', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '54660855-50d3-4f8a-a81d-b7bba6f91ab2'	System	17 Dec 2020 05:05:59
User entered 'No (N)'	System	17 Dec 2020 05:05:59

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-12-17T00:05:56', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '54660855-50d3-4f8a-a81d-b7bba6f91ab2' User entered '17 Dec 2020 00:05:56'	System	17 Dec 2020 05:05:59
	System	17 Dec 2020 05:05:59

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 04:07:45



**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-12-24T00:09:16', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'e968ee13-b826-4226-a586-161f982d305a' User entered 'No (N)'	System	24 Dec 2020 05:09:25
	System	24 Dec 2020 05:09:25

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

Have you been exposed to someone with 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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-12-24T00:09:21', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'e968ee13-b826-4226-a586-161f982d305a' User entered 'No (N)'	System	24 Dec 2020 05:09:25
	System	24 Dec 2020 05:09:25

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-12-24T00:09:23', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'e968ee13-b826-4226-a586-161f982d305a' User entered '24 Dec 2020 00:09:23'	System	24 Dec 2020 05:09:25
	System	24 Dec 2020 05:09:25

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-12-31T09:32:16', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'bd5f4446-8dca-4448-88ca-7a425a65c8e8' User entered 'No (N)'	System	31 Dec 2020 14:32:25
	System	31 Dec 2020 14:32:25

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Have you been exposed to someone with 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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-12-31T09:32:17', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'bd5f4446-8dca-4448-88ca-7a425a65c8e8' User entered 'No (N)'	System	31 Dec 2020 14:32:25
	System	31 Dec 2020 14:32:25



**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2020-12-31T09:32:19', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'bd5f4446-8dca-4448-88ca-7a425a65c8e8' User entered '31 Dec 2020 09:32:19'	System	31 Dec 2020 14:32:25
	System	31 Dec 2020 14:32:25

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-01-09T12:05:19', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '2ddcd3a1-a76d-409f-bbc1-bd54bb5613a8' User entered 'No (N)'	System	09 Jan 2021 17:05:26
	System	09 Jan 2021 17:05:26

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

Have you been exposed to someone with 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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-01-09T12:05:20', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '2ddcd3a1-a76d-409f-bbc1-bd54bb5613a8' User entered 'No (N)'	System	09 Jan 2021 17:05:26
	System	09 Jan 2021 17:05:26

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-01-09T12:05:24', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '2ddcd3a1-a76d-409f-bbc1-bd54bb5613a8' User entered '09 Jan 2021 12:05:24'	System	09 Jan 2021 17:05:26
	System	09 Jan 2021 17:05:26

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 04:07:45



**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-01-14T00:01:25', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '0c15c31a-8c1f-4036-aa08-b10eeff6fee3' User entered 'No (N)'	System	14 Jan 2021 05:01:43
	System	14 Jan 2021 05:01:43

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

Have you been exposed to someone with 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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-01-14T00:01:26', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '0c15c31a-8c1f-4036-aa08-b10eeff6fee3'	System	14 Jan 2021 05:01:43
User entered 'No (N)'	System	14 Jan 2021 05:01:43

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-01-14T00:01:29', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '0c15c31a-8c1f-4036-aa08-b10eeff6fee3' User entered '14 Jan 2021 00:01:29'	System	14 Jan 2021 05:01:43
	System	14 Jan 2021 05:01:43

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 04:07:45



**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-01-23T12:00:33', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '76a01706-0318-4ca2-a7fd-f55440da48eb' User entered 'No (N)'	System	23 Jan 2021 17:01:11
	System	23 Jan 2021 17:01:11

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

Have you been exposed to someone with 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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-01-23T12:00:34', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '76a01706-0318-4ca2-a7fd-f55440da48eb' User entered 'No (N)'	System	23 Jan 2021 17:01:11

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-01-23T12:00:36', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '76a01706-0318-4ca2-a7fd-f55440da48eb' User entered '23 Jan 2021 12:00:36'	System	23 Jan 2021 17:01:11

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-01-28T00:01:23', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'e2f7bffa-668e-4b5d-8427-b6c40c5f8faa' User entered 'No (N)'	System	28 Jan 2021 05:01:52
	System	28 Jan 2021 05:01:52

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

Have you been exposed to someone with 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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-01-28T00:01:24', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'e2f7bffa-668e-4b5d-8427-b6c40c5f8faa'	System	28 Jan 2021 05:01:52
User entered 'No (N)'	System	28 Jan 2021 05:01:52



**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-01-28T00:01:26', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'e2f7bffa-668e-4b5d-8427-b6c40c5f8faa' User entered '28 Jan 2021 00:01:26'	System	28 Jan 2021 05:01:52
	System	28 Jan 2021 05:01:52

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-02-04T00:01:45', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b9d6425e-093a-4834-82f8-817ebaad8aba' User entered 'No (N)'	System	04 Feb 2021 05:02:14
	System	04 Feb 2021 05:02:14

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

Have you been exposed to someone with 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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-02-04T00:01:46', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b9d6425e-093a-4834-82f8-817ebaad8aba' User entered 'No (N)'	System	04 Feb 2021 05:02:14
	System	04 Feb 2021 05:02:14

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-02-04T00:01:48', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'b9d6425e-093a-4834-82f8-817ebaad8aba' User entered '04 Feb 2021 00:01:48'	System	04 Feb 2021 05:02:14
	System	04 Feb 2021 05:02:14

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 04:07:45



**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-02-11T00:01:13', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'a69ff072-e249-49be-a5e4-4ee41e3d85ff' User entered 'No (N)'	System	11 Feb 2021 05:01:58
	System	11 Feb 2021 05:01:58

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Have you been exposed to someone with 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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-02-11T00:01:14', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'a69ff072-e249-49be-a5e4-4ee41e3d85ff'	System	11 Feb 2021 05:01:58
User entered 'No (N)'	System	11 Feb 2021 05:01:58

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-02-11T00:01:16', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'a69ff072-e249-49be-a5e4-4ee41e3d85ff' User entered '11 Feb 2021 00:01:16'	System	11 Feb 2021 05:01:58
	System	11 Feb 2021 05:01:58

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 04:07:45



**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-02-18T00:18:22', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '7c402a09-d2ae-437f-bcf4-a71f7de7f57e' User entered 'No (N)'	System	18 Feb 2021 05:18:28
	System	18 Feb 2021 05:18:28

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

Have you been exposed to someone with 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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-02-18T00:18:23', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '7c402a09-d2ae-437f-bcf4-a71f7de7f57e' User entered 'No (N)'	System	18 Feb 2021 05:18:28

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-02-18T00:18:24', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '7c402a09-d2ae-437f-bcf4-a71f7de7f57e' User entered '18 Feb 2021 00:18:24'	System	18 Feb 2021 05:18:28
	System	18 Feb 2021 05:18:28

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-02-25T00:02:16-05:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '60b86d05-ade6-4b38-a926-005d295cdf38' User entered 'No (N)'	System	25 Feb 2021 05:04:05
	System	25 Feb 2021 05:04:05

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Have you been exposed to someone with 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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-02-25T00:02:18-05:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '60b86d05-ade6-4b38-a926-005d295cdf38' User entered 'No (N)'	System	25 Feb 2021 05:04:05
	System	25 Feb 2021 05:04:05



**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-02-25T00:02:20-05:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '60b86d05-ade6-4b38-a926-005d295cdf38' User entered '25 Feb 2021 05:02:20'	System	25 Feb 2021 05:04:05
	System	25 Feb 2021 05:04:05

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-03-04T00:02:56-05:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '0f0a32ab-c6a2-4148-a83a-fd60745fe9ce'	System	04 Mar 2021 05:05:10
User entered 'No (N)'	System	04 Mar 2021 05:05:10

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

Have you been exposed to someone with 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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-03-04T00:02:58-05:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '0f0a32ab-c6a2-4148-a83a-fd60745fe9ce'	System	04 Mar 2021 05:05:10
User entered 'No (N)'	System	04 Mar 2021 05:05:10

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-03-04T00:03:00-05:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '0f0a32ab-c6a2-4148-a83a-fd60745fe9ce'	System	04 Mar 2021 05:05:10
User entered '04 Mar 2021 00:03:00'	System	04 Mar 2021 05:05:10

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 04:07:45



**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-03-11T00:02:24-05:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '8996bfb1-ec43-4aba-830b-815b573575a6'	System	11 Mar 2021 05:03:50
User entered 'No (N)'	System	11 Mar 2021 05:03:50

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

Have you been exposed to someone with 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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-03-11T00:02:25-05:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '8996bfb1-ec43-4aba-830b-815b573575a6'	System	11 Mar 2021 05:03:50
User entered 'No (N)'	System	11 Mar 2021 05:03:50

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-03-11T00:02:27-05:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '8996bfb1-ec43-4aba-830b-815b573575a6' User entered '11 Mar 2021 00:02:27'	System	11 Mar 2021 05:03:50
	System	11 Mar 2021 05:03:50

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 04:07:45



**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-03-18T00:08:13-04:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'a7df508b-34e0-4d96-bea5-0f8c7d1cae90'	System	18 Mar 2021 04:08:20
User entered 'No (N)'	System	18 Mar 2021 04:08:20

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Have you been exposed to someone with 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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-03-18T00:08:14-04:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'a7df508b-34e0-4d96-bea5-0f8c7d1cae90'	System	18 Mar 2021 04:08:20
User entered 'No (N)'	System	18 Mar 2021 04:08:20

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-03-18T00:08:16-04:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'a7df508b-34e0-4d96-bea5-0f8c7d1cae90'	System	18 Mar 2021 04:08:20
User entered '18 Mar 2021 00:08:16'	System	18 Mar 2021 04:08:20

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-03-25T00:03:07-04:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '5ecc4aa1-0bf8-49d6-8c92-a19504b7e213'	System	25 Mar 2021 04:04:18
User entered 'No (N)'	System	25 Mar 2021 04:04:18

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Have you been exposed to someone with 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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-03-25T00:03:08-04:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '5ecc4aa1-0bf8-49d6-8c92-a19504b7e213'	System	25 Mar 2021 04:04:18
User entered 'No (N)'	System	25 Mar 2021 04:04:18



**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-03-25T00:03:10-04:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '5ecc4aa1-0bf8-49d6-8c92-a19504b7e213' User entered '25 Mar 2021 00:03:10'	System	25 Mar 2021 04:04:18
	System	25 Mar 2021 04:04:18

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-04-03T12:02:09-04:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'f8a7c49d-8859-4e8d-8a9b-28942efcbde0' User entered 'No (N)'	System	03 Apr 2021 16:05:59
	System	03 Apr 2021 16:05:59

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Have you been exposed to someone with 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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-04-03T12:02:11-04:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'f8a7c49d-8859-4e8d-8a9b-28942efcbde0'	System	03 Apr 2021 16:05:59
User entered 'No (N)'	System	03 Apr 2021 16:05:59

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-04-03T12:02:13-04:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'f8a7c49d-8859-4e8d-8a9b-28942efcbde0'	System	03 Apr 2021 16:05:59
User entered '03 Apr 2021 12:02:13'	System	03 Apr 2021 16:05:59

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 04:07:45



**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-04-11T17:59:10-04:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'f007585c-2f45-4bfe-9ee5-462e3a2c538d' User entered 'No (N)'	System	11 Apr 2021 21:59:18
	System	11 Apr 2021 21:59:18

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

Have you been exposed to someone with 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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-04-11T17:59:11-04:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'f007585c-2f45-4bfe-9ee5-462e3a2c538d' User entered 'No (N)'	System	11 Apr 2021 21:59:18
	System	11 Apr 2021 21:59:18

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-04-11T17:59:13-04:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'f007585c-2f45-4bfe-9ee5-462e3a2c538d' User entered '11 Apr 2021 17:59:13'	System	11 Apr 2021 21:59:18
	System	11 Apr 2021 21:59:18

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 04:07:45



**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-04-15T00:28:43-04:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'e26ad5f4-e2a5-43dd-88ef-7e34170fed29'	System	15 Apr 2021 04:28:53
User entered 'No (N)'	System	15 Apr 2021 04:28:53

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

Have you been exposed to someone with 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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-04-15T00:28:44-04:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'e26ad5f4-e2a5-43dd-88ef-7e34170fed29'	System	15 Apr 2021 04:28:53
User entered 'No (N)'	System	15 Apr 2021 04:28:53

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-04-15T00:28:46-04:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'e26ad5f4-e2a5-43dd-88ef-7e34170fed29'	System	15 Apr 2021 04:28:53
User entered '15 Apr 2021 00:28:46'	System	15 Apr 2021 04:28:53

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-04-22T00:02:22-04:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '4af36f1f-b734-4ecd-8335-2f348c465015'	System	22 Apr 2021 04:02:59
User entered 'No (N)'	System	22 Apr 2021 04:02:59

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

Have you been exposed to someone with 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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-04-22T00:02:24-04:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '4af36f1f-b734-4ecd-8335-2f348c465015'	System	22 Apr 2021 04:02:59
User entered 'No (N)'	System	22 Apr 2021 04:02:59



**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-04-22T00:02:27-04:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '4af36f1f-b734-4ecd-8335-2f348c465015'	System	22 Apr 2021 04:02:59
User entered '22 Apr 2021 00:02:27'	System	22 Apr 2021 04:02:59

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-04-29T00:02:19-04:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '880e853d-1cd2-43ea-900e-f5d13fa9ee25'	System	29 Apr 2021 04:03:31
User entered 'No (N)'	System	29 Apr 2021 04:03:31

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Have you been exposed to someone with 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 (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-04-29T00:02:20-04:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '880e853d-1cd2-43ea-900e-f5d13fa9ee25'	System	29 Apr 2021 04:03:31
User entered 'No (N)'	System	29 Apr 2021 04:03:31

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-04-29T00:02:22-04:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: '880e853d-1cd2-43ea-900e-f5d13fa9ee25'	System	29 Apr 2021 04:03:31
User entered '29 Apr 2021 00:02:22'	System	29 Apr 2021 04:03:31

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 04:07:45



**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 04:07:45

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 04:07:45



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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 04:07:45

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 04:07:45

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 04:07:45

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 04:07:45



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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 04:07:45

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 04:07:45

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 04:07:45

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 04:07:45



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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 04:07:45

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 04:07:45

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 04:07:45

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 04:07:45



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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 04:07:45

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 04:07:45

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 04:07:45

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 04:07:45

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 04:07:45

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 04:07:45

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 04:07:45



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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 04:07:45

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 04:07:45

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 04:07:45

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 04:07:45

**US3182292**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 04:07:45

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 04:07:45

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 04:07:45



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 04:07:45

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 04:07:45

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 04:07:45

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 04:07:45



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 04:07:45

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 04:07:45

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 04:07:45

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 04:07:45

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 04:07:45

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 04:07:45



**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 04:07:45



**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 04:07:45



**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 04:07:45



**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 04:07:45



**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 04:07:45



**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 04:07:45



**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 04:07:45



**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 04:07:45



**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 04:07:45



**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 04:07:45



**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 04:07:45



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 04:07:45



**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 04:07:45



**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 04:07:45



**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 04:07:45



**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 04:07:45



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 04:07:45



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 04:07:45



**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 04:07:45



**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 04:07:45



**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 04:07:45

**US3182292**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:01:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:07:45
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 04:07:45

US3182292

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:01:25

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 04:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-03-04T00:03:05-05:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'f9889552-56b4-4b78-b73d-4a8d183745de' User entered 'No (N)'	System	04 Mar 2021 05:05:25
	System	04 Mar 2021 05:05:25

**US3182292**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:01:25**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 04:10:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D314AAAD-2571-4C08-A807-F4A7C6BD139E)', Time: '2021-03-04T00:03:07-05:00', User OID: 'PatientReportedOutcome (US3182292)', ODM File OID: 'f9889552-56b4-4b78-b73d-4a8d183745de' User entered '04 Mar 2021 00:03:07'	System	04 Mar 2021 05:05:25
	System	04 Mar 2021 05:05:25

US3182292

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:16
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	16 Nov 2020 14:40:02



US3182292

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:16
User entered '05 Nov 2020'	Cassie Uminski (b) (4) (b) (4)	16 Nov 2020 14:40:02

US3182292

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:16
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4) (b) (4)	16 Nov 2020 14:40:02

US3182292

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:16
User entered empty.	Cassie Uminski (b) (4) (b) (4)	16 Nov 2020 14:40:02

US3182292

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:10:21
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	16 Nov 2020 14:39:52

**US3182292**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:01:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 23:35:26
User entered 'I'	System	16 Nov 2020 14:39:52

US3182292

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 15:03:17
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:57:42
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	21 Dec 2020 18:45:07

US3182292

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 15:03:17
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:57:42
User entered '08 Dec 2020'	Cassie Uminski (b) (4) (b) (4)	21 Dec 2020 18:45:07

US3182292

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 15:03:17
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:57:42
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4) (b) (4)	21 Dec 2020 18:45:07



US3182292

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 15:03:17
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:57:42
User entered empty.	Cassie Uminski (b) (4) (b) (4)	21 Dec 2020 18:45:07

US3182292

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 15:03:17
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 19:57:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	21 Dec 2020 18:45:12

**US3182292**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:01:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 15:03:17
User entered 'I'	System	21 Dec 2020 18:45:12

US3182292

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 15:03:17
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:18:35
User entered 'Yes (Y)'	Gabby Jacobs (b) (4) (b) (4)	05 Jan 2021 18:02:09

US3182292

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 15:03:17
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:18:35
User entered '05 Jan 2021'	Gabby Jacobs (b) (4) (b) (4)	05 Jan 2021 18:02:09

US3182292

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 15:03:17
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:18:35
User entered 'Contact Made (CONTACT MADE)'	Gabby Jacobs (b) (4) (b) (4)	05 Jan 2021 18:02:09

US3182292

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 15:03:17
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:18:35
User entered empty.	Gabby Jacobs (b) (4) (b) (4)	05 Jan 2021 18:02:09

US3182292

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 15:03:17
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:17:44
User entered 'Yes (Y)'	Gabby Jacobs (b) (4) (b) (4)	05 Jan 2021 18:01:59



**US3182292**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:01:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 15:03:17
User entered 'I'	System	05 Jan 2021 18:01:59

**US3182292**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:01:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 15:03:17
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:40:44
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 20:53:59

US3182292

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 15:03:17
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:40:44
User entered '04 Feb 2021'	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 20:53:59

US3182292

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 15:03:17
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:40:44
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 20:53:59

US3182292

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 15:03:17
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:40:44
User entered empty.	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 20:53:59

US3182292

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 15:03:17
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:40:48
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 20:54:04

**US3182292**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:01:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 15:03:17
User entered 'I'	System	10 Feb 2021 20:54:04

**US3182292**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:01:25**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:39
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 16:50:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User entered 'Yes (Y)'	Jennifer Gaston (b) (4)	27 Feb 2021 16:53:54



US3182292

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:39
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 16:50:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User entered '23 Feb 2021'	Jennifer Gaston (b) (4)	27 Feb 2021 16:53:54

US3182292

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

[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 18:18:39
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 16:50:01
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User entered 'Clinic (Clinic)'	Jennifer Gaston (b) (4)	27 Feb 2021 16:53:54

**US3182292**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:01:25**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:39
User entered 'VISIT4'	System	27 Feb 2021 16:53:54

US3182292

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:39
DataPoint Verified.		07 Apr 2021 16:13:14
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:55:24
User entered 'Yes (Y)'	(b) (4)	
	Cassie Uminski (b) (4)	31 Mar 2021 14:38:15
	(b) (4)	

US3182292

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:39
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:13:14
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:55:24
User entered '23 Feb 2021'	Cassie Uminski (b) (4)	31 Mar 2021 14:38:15

US3182292

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:39
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:13:14
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:55:24
User entered '12:49'	Cassie Uminski (b) (4)	31 Mar 2021 14:38:15

**US3182292**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:01:25**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:39
User entered '23 Feb 2021 12:49'	System	31 Mar 2021 14:38:15

US3182292

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:39
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:13:14
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:55:24
User entered '98.0' F	Cassie Uminski (b) (4)	31 Mar 2021 14:38:15



US3182292

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:39
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:13:14
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:55:24
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	31 Mar 2021 14:38:15

US3182292

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:39
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:13:14
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:55:24
User entered empty.	Cassie Uminski (b) (4)	31 Mar 2021 14:38:15

US3182292

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:39
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:13:14
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:55:24
User entered '60'	Cassie Uminski (b) (4)	31 Mar 2021 14:38:15

**US3182292**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:01:25**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:39
User entered 'bpm'	System	31 Mar 2021 14:38:15

US3182292

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:39
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:13:14
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:55:24
User entered '16'	Cassie Uminski (b) (4)	31 Mar 2021 14:38:15

US3182292

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:39
User entered 'breaths/min'	System	31 Mar 2021 14:38:15

US3182292

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:39
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:13:14
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:55:24
User entered '122'	Cassie Uminski (b) (4)	31 Mar 2021 14:38:15

US3182292

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:39
User entered 'mmHg'	System	31 Mar 2021 14:38:15



US3182292

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:39
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:13:14
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:55:24
User entered '76'	Cassie Uminski (b) (4)	31 Mar 2021 14:38:15

US3182292

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:39
User entered 'mmHg'	System	31 Mar 2021 14:38:15

US3182292

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:39

US3182292

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:39

US3182292

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:39
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 16:50:12
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User entered 'Yes (Y)'	Jennifer Gaston (b) (4)	27 Feb 2021 16:57:17

US3182292

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:39
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 16:50:12
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User entered '23 Feb 2021'	Jennifer Gaston (b) (4)	27 Feb 2021 16:57:17

US3182292

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:39
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 10:41:44
User closed query 'Please complete with OL1 information per guidelines 23Feb 13:05 ' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 10:41:40
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:15:26
Query 'Please complete with OL1 information per guidelines 23Feb 13:05 ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4)	11 Mar 2021 18:42:59
Signature has been broken.	Cassie Uminski (b) (4)	11 Mar 2021 18:42:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	11 Mar 2021 18:42:54
User opened query 'Please complete with OL1 information per guidelines 23Feb 13:05 ' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 16:48:50
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User entered 'No (N)'	Jennifer Gaston (b) (4)	27 Feb 2021 16:57:59

US3182292

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:39
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 10:41:44
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:15:26
Signature has been broken.	Cassie Uminski (b) (4)	11 Mar 2021 18:42:54
User entered '23 Feb 2021' reason for change: Data Entry Error	Cassie Uminski (b) (4)	11 Mar 2021 18:42:54
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User entered empty.	Jennifer Gaston (b) (4)	27 Feb 2021 16:57:59



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Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:39
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 10:41:44
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:15:26
Signature has been broken.	Cassie Uminski (b) (4)	11 Mar 2021 18:42:54
User entered '13:05' reason for change: Data Entry Error	Cassie Uminski (b) (4)	11 Mar 2021 18:42:54
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User entered empty.	Jennifer Gaston (b) (4)	27 Feb 2021 16:57:59

**US3182292**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:01:25**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:39
User entered '23 Feb 2021 13:05'	System	11 Mar 2021 18:42:54
User entered empty.	System	27 Feb 2021 16:57:59

US3182292

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:39
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 16:50:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User entered 'Yes (Y)'	Jennifer Gaston (b) (4)	27 Feb 2021 16:58:04

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Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:25

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:39
User entered 'I'	System	27 Feb 2021 16:58:04

US3182292

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	22 Apr 2021 16:15:27
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	22 Apr 2021 13:35:14

US3182292

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	22 Apr 2021 16:15:27
	(b) (4)	
User entered '08 Apr 2021'	Cassie Uminski (b) (4)	22 Apr 2021 13:35:14
	(b) (4)	

**US3182292**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:01:25**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	22 Apr 2021 16:15:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Cassie Uminski (b) (4)	22 Apr 2021 13:35:14

US3182292

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	22 Apr 2021 16:15:27
User entered empty.	Cassie Uminski (b) (4) (b) (4)	22 Apr 2021 13:35:14



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Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	22 Apr 2021 16:15:27
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	22 Apr 2021 13:35:19

**US3182292**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:01:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Apr 2021 13:35:19

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:01:25

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:46:46
User entered '25 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	26 Aug 2020 18:08:07

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:01:25

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:46:46
User entered '10:30' reason for change: Data Entry Error	Cassie Uminski (b) (4)	28 Aug 2020 19:24:35
User entered '14:48'	(b) (4) Cassie Uminski (b) (4) (b) (4)	26 Aug 2020 18:08:07

**US3182292**

**Folder: Covid-19 Assessment 25 Aug 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:01:25**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User entered '25 Aug 2020 10:30'	System	28 Aug 2020 19:24:35
User entered '25 Aug 2020 14:48'	System	26 Aug 2020 18:08:07

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:01:25

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:46:46
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Cassie Uminski (b) (4) (b) (4)	26 Aug 2020 18:08:07

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:01:25

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:46:46
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	26 Aug 2020 18:08:07

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User entered 'Day 1 (Day 1)'	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:21:34



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:49:24
User entered '23 Aug 2020'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:21:34

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:49:26
User entered '0'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:21:34

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 14:59:00
User closed query 'Per CDM; please review entire log form and provide any missing data or record as Not Done.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 18:37:17
Query 'Per CDM; please review entire log form and provide any missing data or record as Not Done.' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	24 Nov 2020 16:38:44
DataPoint Un-verified.	Cassie Uminski (b) (4) (b) (4)	24 Nov 2020 16:38:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Cassie Uminski (b) (4) (b) (4)	24 Nov 2020 16:38:30
User opened query 'Per CDM; please review entire log form and provide any missing data or record as Not Done.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:29:25
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 13:49:29
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:21:34

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User entered '%'	System	24 Nov 2020 16:38:30
User entered empty.	System	06 Sep 2020 16:21:34

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 14:59:02
DataPoint Un-verified.	Cassie Uminski (b) (4)	24 Nov 2020 16:38:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Cassie Uminski (b) (4)	24 Nov 2020 16:38:51
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 13:49:30
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:21:34

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:49:39
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:21:34

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:49:41
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:21:34

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:49:46
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:21:34



US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:49:49
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:56:55
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:21:34

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:49:58
User entered 'Mild (Mild)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:21:34

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:50:01
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:56:55
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:21:34

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:50:14
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:56:55
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:21:34

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:50:19
User entered 'Mild (Mild)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:21:34

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:50:24
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 12:56:55
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:21:34

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:50:29
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:56:55
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:21:34

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:50:33
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:21:34



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:50:37
User entered 'Mild (Mild)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:21:34

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:50:41
User entered 'Mild (Mild)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:21:34

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:50:43
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:03:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:21:34

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:50:48
User entered 'Mild (Mild)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:21:34

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User closed query 'Please clarify as CRF has none but source states mild starting 23Aug2020. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:10:00
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 18:09:58
Query 'Please clarify as CRF has none but source states mild starting 23Aug2020. ' answered with 'corrected' (Site from CRA).	Amy Maroun (b) (4) (b) (4)	26 Oct 2020 17:45:23
DataPoint Un-verified.	Amy Maroun (b) (4) (b) (4)	26 Oct 2020 17:45:13
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amy Maroun (b) (4) (b) (4)	26 Oct 2020 17:45:13
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:18:54
User opened query 'Please clarify as CRF has none but source states mild starting 23Aug2020. ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 13:49:10
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:03:00
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:21:34

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User entered 'Day 2 (Day 2)'	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:23:37

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:50:56
User entered '24 Aug 2020'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:23:37

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:51:16
User entered '0'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:23:37



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 14:59:10
DataPoint Un-verified.	Cassie Uminski (b) (4)	24 Nov 2020 16:39:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Cassie Uminski (b) (4)	24 Nov 2020 16:39:02
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 13:51:17
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:23:37

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User entered '%'	System	24 Nov 2020 16:39:02
User entered empty.	System	06 Sep 2020 16:23:37

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 14:59:11
DataPoint Un-verified.	Cassie Uminski (b) (4)	24 Nov 2020 16:39:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Cassie Uminski (b) (4)	24 Nov 2020 16:39:02
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 13:51:19
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:23:37

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:51:13
User entered 'Mild (Mild)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:23:37

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:51:24
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:23:37

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:51:27
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:23:37

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:51:33
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:56:55
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:23:37

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:51:37
User entered 'Mild (Mild)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:23:37



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:51:41
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:56:55
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:23:37

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:51:44
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:56:55
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:23:37

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:51:48
User entered 'Mild (Mild)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:23:37

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:51:51
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:56:55
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:23:37

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:51:55
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:56:55
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:23:37

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:52:05
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:23:37

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:52:08
User entered 'Mild (Mild)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:23:37

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:52:12
User entered 'Mild (Mild)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:23:37



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:52:15
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:03:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:23:37

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:52:21
User entered 'Mild (Mild)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:23:37

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User closed query 'Please clarify as CRF has none but source states start on 23Aug2020 and continuing. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:10:18
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 18:10:15
Query 'Please clarify as CRF has none but source states start on 23Aug2020 and continuing. ' answered with 'updated' (Site from CRA).	Amy Maroun (b) (4) (b) (4)	26 Oct 2020 17:46:31
DataPoint Un-verified.	Amy Maroun (b) (4) (b) (4)	26 Oct 2020 17:46:04
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amy Maroun (b) (4) (b) (4)	26 Oct 2020 17:46:04
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:18:54
User opened query 'Please clarify as CRF has none but source states start on 23Aug2020 and continuing. ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 13:53:25
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:03:00
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:23:37

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User entered 'Day 3 (Day 3)'	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:24:29

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:54:17
User entered '25 Aug 2020'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:24:29

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:54:21
User entered '0'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:24:29

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 14:59:20
DataPoint Un-verified.	Cassie Uminski (b) (4)	24 Nov 2020 16:39:10
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Cassie Uminski (b) (4)	24 Nov 2020 16:39:10
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 13:54:22
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:24:29

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User entered '%'	System	24 Nov 2020 16:39:10
User entered empty.	System	06 Sep 2020 16:24:29



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:12:06
Query 'The only source I see for 25Aug2020 is the clinic visit where the temp was 99.1. CRF has 101.6. Please clarify. ' canceled (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 14:12:03
User opened query 'The only source I see for 25Aug2020 is the clinic visit where the temp was 99.1. CRF has 101.6. Please clarify. ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 14:03:34
User entered '101.6' F	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:24:29

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:03:48
User entered 'Mild (Mild)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:24:29

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:04:00
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:24:29

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:04:02
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 12:55:00
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:24:29

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:04:17
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:56:55
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:24:29

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:05:17
User entered 'Mild (Mild)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:24:29

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:05:22
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 12:56:55
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:24:29

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:05:25
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:56:55
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:24:29



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:05:30
User entered 'Mild (Mild)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:24:29

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:05:33
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:56:55
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:24:29

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:05:34
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:56:55
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:24:29

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:05:39
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:24:29

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:05:48
User entered 'Mild (Mild)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:24:29

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:05:54
User entered 'Mild (Mild)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:24:29

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:05:56
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:03:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:24:29

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:06:03
User entered 'Mild (Mild)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:24:29



US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User closed query 'Please clarify as source has sore throat starting 23Aug2020 and CRF has none. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:10:30
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 18:10:28
Query 'Please clarify as source has sore throat starting 23Aug2020 and CRF has none. ' answered with 'updated' (Site from CRA).	Amy Maroun (b) (4) (b) (4)	26 Oct 2020 17:48:01
DataPoint Un-verified.	Amy Maroun (b) (4) (b) (4)	26 Oct 2020 17:47:52
User entered 'Mild (Mild)' reason for change: Data Entry Error	Amy Maroun (b) (4) (b) (4)	26 Oct 2020 17:47:52
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:18:54
User opened query 'Please clarify as source has sore throat starting 23Aug2020 and CRF has none. ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 14:06:47
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:03:00
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:24:29

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User entered 'Day 4 (Day 4)'	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:27:05

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:07:45
User entered '26 Aug 2020'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:27:05

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:07:46
User entered '0'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:27:05

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 14:59:27
DataPoint Un-verified.	Cassie Uminski (b) (4)	24 Nov 2020 16:39:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Cassie Uminski (b) (4)	24 Nov 2020 16:39:33
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:07:48
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:27:05

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User entered '%'	System	24 Nov 2020 16:39:33
User entered empty.	System	06 Sep 2020 16:27:05

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 14:59:28
DataPoint Un-verified.	Cassie Uminski (b) (4)	24 Nov 2020 16:39:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Cassie Uminski (b) (4)	24 Nov 2020 16:39:33
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:07:50
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:27:05

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:07:58
User entered 'Mild (Mild)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:27:05



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:08:02
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:27:05

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:08:06
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:27:05

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:08:16
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:56:55
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:27:05

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:08:20
User entered 'Mild (Mild)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:27:05

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:08:23
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:56:55
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:27:05

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:08:28
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:56:55
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:27:05

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:08:37
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:56:55
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:27:05

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:08:43
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:56:55
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:27:05



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:08:45
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:56:55
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:27:05

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:08:47
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:27:05

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:08:51
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:27:05

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:08:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:27:05

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:09:06
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:03:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:27:05

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:09:09
User entered 'Mild (Mild)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:27:05

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:09:10
User entered 'Mild (Mild)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:27:05

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User entered 'Day 5 (Day 5)'	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:28:21



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:13:42
User entered '27 Aug 2020'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:28:21

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '0'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:28:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:13:47
User entered '99'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:28:21

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User entered '%'	System	06 Sep 2020 16:28:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:13:49
User entered '98.4' F	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:28:21

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:13:56
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:28:21

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:28:21

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:28:21



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:56:55
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:28:21

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:56:55
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:28:21

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:56:55
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:28:21

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:56:55
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:28:21

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:56:55
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:28:21

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:56:55
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:28:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:56:55
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:28:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:28:21



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:28:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:28:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:03:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:28:21

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:03:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:28:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'Mild (Mild)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:28:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User entered 'Day 6 (Day 6)'	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '28 Aug 2020'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '0'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:21



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Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '98'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User entered '%'	System	06 Sep 2020 16:29:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '99.0' F	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:21



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:21

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:03:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:21



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:03:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:03:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:21

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'Mild (Mild)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:21

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User entered 'Day 7 (Day 7)'	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:57

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '29 Aug 2020'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:57

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '0'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:57

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '95'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:57

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User entered '%'	System	06 Sep 2020 16:29:57



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '98.5' F	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:57

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:57

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:57

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:57

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:57

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:57

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:57

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:57



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:57

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:57

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:57

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:57

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:57

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:03:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:57

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:03:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:57

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:03:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:57



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:03:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:29:57

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User entered 'Day 8 (Day 8)'	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:30:39

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '30 Aug 2020'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:30:39

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '0'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:30:39

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '98'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:30:39

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User entered '%'	System	06 Sep 2020 16:30:39

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '97.9' F	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:30:39

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:30:39



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:30:39

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:30:39

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:30:39

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:30:39

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:30:39

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:30:39

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:30:39

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:30:39



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:30:39

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:30:39

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:30:39

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:03:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:30:39

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:03:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:30:39

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:03:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:30:39

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:03:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:30:39

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User entered 'Day 9 (Day 9)'	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:31:12



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '31 Aug 2020'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:31:12

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '0'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:31:12

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '94'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:31:12

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User entered '%'	System	06 Sep 2020 16:31:12

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '98.5' F	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:31:12

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:31:12

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:31:12

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:31:12



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: New Information	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:01:01
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:31:12

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:31:12

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:31:12

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:31:12

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:31:12

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:31:12

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:31:12

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:31:12



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:31:12

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:03:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:31:12

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:03:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:31:12

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:03:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:31:12

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:03:00
User entered empty.	(b) (4) Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:31:12

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User entered 'Day 10 (Day 10)'	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '01 Sep 2020'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 12:55:00

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '0'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 12:55:00



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '96'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 12:55:00

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User entered '%'	System	10 Sep 2020 12:55:00

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '98.0' F	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 12:55:00

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:57:21
User entered empty.	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:57:21
User entered empty.	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 12:57:21
User entered empty.	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	(b) (4) Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 12:55:00

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Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:01:01
User entered empty.	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:03:00
User entered empty.	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:03:00
User entered empty.	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:03:00
User entered empty.	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)' reason for change: Data Entry Error	Brooke Glivar (b) (4)	10 Sep 2020 13:03:00
User entered empty.	Brooke Glivar (b) (4)	10 Sep 2020 12:55:00

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User entered 'Day 11 (Day 11)'	Brooke Glivar (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '02 Sep 2020'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '0'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '94'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User entered '%'	System	10 Sep 2020 13:15:44



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '98.5' F	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User entered 'Day 12 (Day 12)'	Brooke Glivar (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '03 Sep 2020'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '0'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '98'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User entered '%'	System	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '99.0' F	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44



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Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User entered 'Day 13 (Day 13)'	Brooke Glivar (b) (4)	10 Sep 2020 13:15:44



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '04 Sep 2020'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '0'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '95'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User entered '%'	System	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '99.0' F	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44



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Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User entered 'Day 14 (Day 14)'	Brooke Glivar (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '05 Sep 2020'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '0'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '95'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User entered '%'	System	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '98.4' F	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44



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Generated On: 11 Aug 2021 22:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44



US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User entered 'Day 15 (Day 15)'	Brooke Glivar (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '06 Sep 2020'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '0'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '98'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User entered '%'	System	10 Sep 2020 13:15:44



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '97.9' F	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44



US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:01:25

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User entered 'Day 16 (Day 16)'	Brooke Glivar (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:01:25

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
Query 'Per CDM: it appears additional records of symptoms may be missing as there is a Convalescence Visit day 28 recorded with date of 22SEP2020. Please reconcile or clarify.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:05:44
User opened query 'Per CDM: it appears additional records of symptoms may be missing as there is a Convalescence Visit day 28 recorded with date of 22SEP2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 01:31:25
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '07 Sep 2020'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:01:25

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '0'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '94'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:01:25

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User entered '%'	System	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:01:25

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered '96.9' F	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:01:25

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:01:25

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:01:25

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:01:25

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:01:25

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:01:25

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:01:25

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:01:25

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44



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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:01:25

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:01:25

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:01:25

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:01:25

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:01:25

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:01:25

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:01:25

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:18:54
User entered 'None (None)'	Brooke Glivar (b) (4) (b) (4)	10 Sep 2020 13:15:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:01:25

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:19:20
User entered '25 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	26 Aug 2020 18:10:09



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Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:01:25

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:19:20
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	26 Aug 2020 18:10:09

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Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:01:25

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:19:20
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).	Ipsita Abalokita (b) (4) (b) (4)	03 Sep 2020 15:02:12
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'Updated AE's' (Site from System).	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:46:22
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	01 Sep 2020 15:37:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:37:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	27 Aug 2020 08:14:47
Query 'Data is required. Please complete.' answered with 'This will be completed once results are back' (Site from System).	Cassie Uminski (b) (4) (b) (4)	26 Aug 2020 18:15:44
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 18:15:31
User entered empty; reason for change Data Entry Error	Cassie Uminski (b) (4) (b) (4)	26 Aug 2020 18:15:31
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	26 Aug 2020 18:10:09

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Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:01:25

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:19:20
User entered '25 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	26 Aug 2020 18:10:09

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Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:01:25

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:19:20
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Cassie Uminski (b) (4) (b) (4)	26 Aug 2020 18:10:09

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Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:01:25

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:19:20
User entered empty.	Cassie Uminski (b) (4) (b) (4)	26 Aug 2020 18:10:09

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Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:01:25

[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)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:19:20
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	26 Aug 2020 18:10:09

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Form: COVID Diagnostic Test

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:19:20
User entered empty.	Cassie Uminski (b) (4) (b) (4)	26 Aug 2020 18:10:09

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Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID Diagnostic Test

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:19:20
User entered empty.	Cassie Uminski (b) (4) (b) (4)	26 Aug 2020 18:10:09



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Form: COVID Diagnostic Test

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User entered '1'	System	01 Sep 2020 15:37:54
User entered '0'	System	26 Aug 2020 18:10:09

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered 'No (N)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

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Form: Covid-19 Severity Assessment

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Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered 'No (N)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25



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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

Did the subject have Oxygen Saturation of SpO2  $\leq$  93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered 'No (N)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered 'No (N)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25



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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered 'No (N)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 16:37:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Sep 2020 16:37:49
User entered 'No (N)' reason for change: Data Entry Error	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:49
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 16:37:25
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

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Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25



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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

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Form: Covid-19 Severity Assessment

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25



US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered 'No (N)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[Evidence of Shock Requires](#)

[Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered 'No (N)' reason for change: Data Entry Error	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 22:29:40
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered 'No (N)' reason for change: Data Entry Error	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 22:29:40
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25



US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered 'No (N)' reason for change: Data Entry Error	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 22:29:40
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered 'No (N)' reason for change: Data Entry Error	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 22:29:40
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered 'No (N)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:21:12
User closed query 'Per CDM: Please provide a response for 'Radiographical Evidence'.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 03:39:02
Query 'Per CDM: Please provide a response for 'Radiographical Evidence'.' answered with 'Updated per query' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	15 Jan 2021 14:51:19
DataPoint Un-verified.	Cassie Uminski (b) (4) (b) (4)	15 Jan 2021 14:51:10
User entered 'No (N)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	15 Jan 2021 14:51:10
User opened query 'Per CDM: Please provide a response for 'Radiographical Evidence'.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 06:54:12
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25



US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered 'No (N)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:01:25

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:39:12
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:37:25

US3182292

Folder: Covid-19 Assessment 25 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:01:25

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:25
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:40:46
User entered 'No (N)'	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 02:18:40

US3182292

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:01:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:32:45

**US3182292**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:01:25**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:24:54
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:32:45

**US3182292**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:01:25**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:24:54
User entered '27 Aug 2020'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:32:45



US3182292

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:01:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:32:45

**US3182292**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:01:25**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:24:54
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:32:45

**US3182292**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:01:25**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:24:54
User entered '29 Aug 2020'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:32:45

US3182292

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:01:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:32:45

**US3182292**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:01:25**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:24:54
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:32:45

**US3182292**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:01:25**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:24:54
User entered '31 Aug 2020'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:32:45

**US3182292**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:01:25**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:32:45

**US3182292**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:01:25**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:24:54
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:32:45



**US3182292**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:01:25**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:24:54
User entered '2 Sep 2020'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:32:45

US3182292

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:01:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:32:45

**US3182292**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 22:01:25**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:24:54
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:32:45

**US3182292**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 22:01:25**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:24:54
User entered '7 Sep 2020'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:32:45

**US3182292**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:01:25**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:32:45

US3182292

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:01:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:24:54
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:32:45

**US3182292**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:01:25**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:24:54
User entered '14 Sep 2020'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:32:45

US3182292

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:01:25

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:32:45



US3182292

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:01:25

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:24:54
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Oct 2020 14:32:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Oct 2020 14:32:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:32:56
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Oct 2020 14:32:45
User entered empty.	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:32:45

US3182292

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:01:25

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22SEP2020 is recorded as Illness Visit Day 28 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 04:26:05
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22SEP2020 is recorded as Illness Visit Day 28 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'The site did not have a kit for Day 28 illness so an unscheduled kit was used' (Site from DM).	Amy Maroun (b) (4) (b) (4)	29 Oct 2020 02:21:58
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22SEP2020 is recorded as Illness Visit Day 28 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 10:37:44
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:24:54
User entered '22 Sep 2020'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:32:45

US3182292

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:40:35
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:17:23

US3182292

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:40:35
User entered '25 Aug 2020'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:17:23

US3182292

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:40:35
User entered 'Clinic (Clinic)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:17:23

US3182292

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:27
User entered 'SICKD1'	System	06 Sep 2020 16:17:23

US3182292

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:43:02
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:18:45

US3182292

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:43:02
User entered '25 Aug 2020'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:18:45



US3182292

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:43:02
User entered '15:00'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:18:45

US3182292

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:27
User entered '25 Aug 2020 15:00'	System	06 Sep 2020 16:18:45

US3182292

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:43:02
User entered '179.6' cm	Amy Maroun (b) (4)	06 Sep 2020 16:18:45
DataPoint set to visible.	(b) (4) System	06 Sep 2020 16:17:23

US3182292

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:43:02
User entered '65.7' kg	Amy Maroun (b) (4)	06 Sep 2020 16:18:45
DataPoint set to visible.	(b) (4) System	06 Sep 2020 16:17:23

US3182292

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:43:02
User entered '99.1' F	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:18:45

US3182292

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:43:02
User entered 'Oral (Oral)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:18:45

US3182292

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:43:02
User entered empty.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:18:45

US3182292

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:43:02
User entered '83'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:18:45



**US3182292**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:01:25**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:27
User entered 'bpm'	System	06 Sep 2020 16:18:45

US3182292

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:43:02
User entered '16'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:18:45

US3182292

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:27
User entered 'breaths/min'	System	06 Sep 2020 16:18:45

US3182292

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:43:02
User entered '108'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:18:45

US3182292

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:27
User entered 'mmHg'	System	06 Sep 2020 16:18:45

US3182292

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:43:02
User entered '63'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:18:45

US3182292

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:27
User entered 'mmHg'	System	06 Sep 2020 16:18:45

US3182292

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:27



US3182292

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:27

US3182292

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:43:25
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:19:12

US3182292

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:43:25
User entered '25 Aug 2020'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:19:12

US3182292

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:01:25

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:44:20
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:19:32

US3182292

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:01:25

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:27
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:44:20
User entered '25 Aug 2020'	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:19:32

US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:19:59
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	23 Sep 2020 11:32:48

US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User closed query 'Per SARS-CoV-2 Lab Recon: it appears GCL has a blood sample dated 22SEP2020 as an Unscheduled Visit but there is no record in EDC with this date. Please review and reconcile or clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 03:06:51
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:19:59
Query 'Per SARS-CoV-2 Lab Recon: it appears GCL has a blood sample dated 22SEP2020 as an Unscheduled Visit but there is no record in EDC with this date. Please review and reconcile or clarify.' answered with 'the unscheduled kit was used for the Day 28 Illness visit as the site never received kit E' (Site from DM).	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 15:08:03
User opened query 'Per SARS-CoV-2 Lab Recon: it appears GCL has a blood sample dated 22SEP2020 as an Unscheduled Visit but there is no record in EDC with this date. Please review and reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 13:21:43
User entered '22 Sep 2020' reason for change: Data Entry Error	Amy Maroun (b) (4) (b) (4)	23 Sep 2020 11:33:05
User entered '23 Sep 2020'	Amy Maroun (b) (4) (b) (4)	23 Sep 2020 11:32:48

US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:19:59
User entered 'Clinic (Clinic)'	Amy Maroun (b) (4) (b) (4)	23 Sep 2020 11:32:48



US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:41
User entered 'SICKD28'	System	23 Sep 2020 11:32:48

US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:21:14
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	23 Sep 2020 11:36:12

US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:21:14
User entered '22 Sep 2020'	Amy Maroun (b) (4) (b) (4)	23 Sep 2020 11:36:12

US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:21:14
User entered '15:07'	Amy Maroun (b) (4) (b) (4)	23 Sep 2020 11:36:12

US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:41
User entered '22 Sep 2020 15:07'	System	23 Sep 2020 11:36:12

US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:21:14
User entered '179.6' cm	Amy Maroun (b) (4)	23 Sep 2020 11:36:12
DataPoint set to visible.	(b) (4) System	23 Sep 2020 11:32:48

US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:21:14
User entered '65.4' kg	Amy Maroun (b) (4)	23 Sep 2020 11:36:12
DataPoint set to visible.	(b) (4) System	23 Sep 2020 11:32:48

US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:21:14
User entered '98.2' F	Amy Maroun (b) (4) (b) (4)	23 Sep 2020 11:36:12



US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:21:14
User entered 'Oral (Oral)'	Amy Maroun (b) (4) (b) (4)	23 Sep 2020 11:36:12

US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:21:14
User entered empty.	Amy Maroun (b) (4) (b) (4)	23 Sep 2020 11:36:12

US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:21:14
User entered '65'	Amy Maroun (b) (4) (b) (4)	23 Sep 2020 11:36:12

US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:41
User entered 'bpm'	System	23 Sep 2020 11:36:12

US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:21:14
User entered '14'	Amy Maroun (b) (4) (b) (4)	23 Sep 2020 11:36:12

US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:41
User entered 'breaths/min'	System	23 Sep 2020 11:36:12

US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:21:14
User entered '101'	Amy Maroun (b) (4) (b) (4)	23 Sep 2020 11:36:12

US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:41
User entered 'mmHg'	System	23 Sep 2020 11:36:12



US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:21:14
User entered '69'	Amy Maroun (b) (4) (b) (4)	23 Sep 2020 11:36:12

US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:41
User entered 'mmHg'	System	23 Sep 2020 11:36:12

US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:41

US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:41

US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:21:52
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	23 Sep 2020 11:36:54

US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:21:52
User entered '22 Sep 2020'	Amy Maroun (b) (4) (b) (4)	23 Sep 2020 11:36:54

US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:01:25

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User closed query 'Per GCL Lab Recon: GCL has an Unscheduled SARS sample with date of 22SEP2020; however, this date is recorded for Convalescence Visit Day 28 in EDC. Please confirm Convalescence Visit Day 28 is 09SEP2020 or clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 03:07:52
Query 'Per GCL Lab Recon: GCL has an Unscheduled SARS sample with date of 22SEP2020; however, this date is recorded for Convalescence Visit Day 28 in EDC. Please confirm Convalescence Visit Day 28 is 09SEP2020 or clarify.' answered with 'The site had not received Kit E (Day 28 Illness) so an unscheduled visit kit was used' (Site from DM).	Amy Maroun (b) (4) (b) (4)	26 Oct 2020 17:43:35
User opened query 'Per GCL Lab Recon: GCL has an Unscheduled SARS sample with date of 22SEP2020; however, this date is recorded for Convalescence Visit Day 28 in EDC. Please confirm Convalescence Visit Day 28 is 09SEP2020 or clarify.' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 23:30:05
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:22:04
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:33:19

US3182292

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:01:25

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:10:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:22:04
User entered '22 Sep 2020'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:33:19



**US3182292**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:01:25**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:54:51
User entered 'Yes (Y)'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:46:35

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:54:51
User entered '23 Feb 2021'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:46:35

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:54:51
User entered 'Clinic (Clinic)'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:46:35

**US3182292**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:01:25**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User entered 'UNBLND_DECIDE'	System	27 Feb 2021 16:46:35

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:01:25

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:15:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:57:25
User entered '23 Feb 2021'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:47:09

**US3182292**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:01:25**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 10:41:06
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:15:26
User entered '0'	Cassie Uminski (b) (4)	11 Mar 2021 18:41:05
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:35:28

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:01:25

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:15:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:57:25
User entered 'Yes (Y)'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:47:09

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:01:25

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 10:41:10
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:15:26
User entered 'Amendment 6 or later (Amendment 6 or later)'	Cassie Uminski (b) (4)	11 Mar 2021 18:41:05
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:35:28



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:01:25

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:15:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:57:25
User entered '23 Feb 2021'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:47:09

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:01:25

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:15:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:57:25
User entered 'Placebo (Placebo)'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:47:09

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:01:25

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:15:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:57:25
User entered 'Placebo (Placebo)'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:47:09

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:01:25

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User closed query 'Please clarify as subject did not receive dose 2. ' (Site from CRA).	(b) (4), (b) (6)	12 Mar 2021 10:40:33
DataPoint Verified.	(b) (4), (b) (6)	12 Mar 2021 10:40:29
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:15:26
Query 'Please clarify as subject did not receive dose 2. ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4)	11 Mar 2021 18:41:47
User entered 'Not Administered (NA)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	11 Mar 2021 18:41:28
User opened query 'Please clarify as subject did not receive dose 2. ' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 19:57:46
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 19:57:27
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:57:25
User entered 'Placebo (Placebo)'	Jennifer Gaston (b) (4)	27 Feb 2021 16:47:09

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:01:25

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	11 Mar 2021 22:15:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:57:25
User entered 'Yes (Y)'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:47:09

**US3182292**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:01:25**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User entered '1'	System	27 Feb 2021 16:47:09

**US3182292**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:01:25**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User entered 'I'	System	27 Feb 2021 16:47:09

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:00:17
User entered '179.6' cm	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:49:23



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:25

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:00:17
User entered '65.7' kg	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:49:23

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:25

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User entered '20.36820'	System	27 Feb 2021 16:49:23
DataPoint set to visible.	System	27 Feb 2021 16:47:09

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:00:17
User entered '179.6' cm	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:49:23

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:25

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:00:17
User entered '65.7' kg	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:49:23

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:25

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User entered '20.36820'	System	27 Feb 2021 16:49:23
DataPoint set to visible.	System	27 Feb 2021 16:47:09

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User accepted default value 'Pre-Dose (PREDOSE)'	Jennifer Gaston (b) (4)	27 Feb 2021 16:49:23
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:00:17
User entered 'Yes (Y)'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:49:23

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:00:17
User entered '23 Feb 2021'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:49:23



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:00:17
User entered '12:49'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:49:23

**US3182292**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:01:25**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User entered '23 Feb 2021 12:49'	System	27 Feb 2021 16:49:23

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:00:17
User entered '98.0' F	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:49:23

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:00:17
User entered 'Oral (Oral)'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:49:23

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:00:17
User entered empty.	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:49:23

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:00:17
User entered '60'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:49:23

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User entered 'bpm'	System	27 Feb 2021 16:49:23

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:00:17
User entered '16'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:49:23



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User entered 'breaths/min'	System	27 Feb 2021 16:49:23

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:00:17
User entered '122'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:49:23

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User entered 'mmHg'	System	27 Feb 2021 16:49:23

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:00:17
User entered '76'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:49:23

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User entered 'mmHg'	System	27 Feb 2021 16:49:23

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:25

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:00:17
User entered '179.6' cm	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:49:23

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:25

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:00:17
User entered '65.7' kg	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:49:23

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:25

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User entered '20.36820'	System	27 Feb 2021 16:49:23
DataPoint set to visible.	System	27 Feb 2021 16:47:09



US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User accepted default value 'Post-Dose (POSTDOSE)'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:49:23

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:00:17
User entered 'Yes (Y)'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:49:23

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:00:17
User entered '23 Feb 2021'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:49:23

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:00:17
User entered '14:22'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:49:23

**US3182292**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:01:25**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User entered '23 Feb 2021 14:22'	System	27 Feb 2021 16:49:23

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:00:17
User entered '97.8' F	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:49:23

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:00:17
User entered 'Oral (Oral)'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:49:23

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:00:17
User entered empty.	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:49:23



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:00:17
User entered '60'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:49:23

**US3182292**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:01:25**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User entered 'bpm'	System	27 Feb 2021 16:49:23

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:00:17
User entered '16'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:49:23

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User entered 'breaths/min'	System	27 Feb 2021 16:49:23

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:00:17
User entered '136'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:49:23

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User entered 'mmHg'	System	27 Feb 2021 16:49:23

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:00:17
User entered '76'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:49:23

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User entered 'mmHg'	System	27 Feb 2021 16:49:23



US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:59:05
User entered 'Yes (Y)'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:52:23

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:25

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:59:05
User entered '23 Feb 2021'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:52:23

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:58:59
User entered 'Yes (Y)'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:52:45

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:58:59
User entered empty.	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:52:45

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:58:59
User entered empty.	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:52:45

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User entered 'mRNA-1273'	System	27 Feb 2021 16:52:45
DataPoint set to visible.	System	27 Feb 2021 16:47:09

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:58:59
User entered '23 Feb 2021'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:52:45

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:58:59
User entered '13:52'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:52:45



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User entered '23 Feb 2021 13:52'	System	27 Feb 2021 16:52:45

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:58:59
User entered 'Left Arm (LEFT ARM)'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:52:45

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 19:58:59
User entered 'ONCE'	System	27 Feb 2021 16:52:45

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User entered 'INTRAMUSCULAR'	System	27 Feb 2021 16:52:45

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:58:38
User entered 'Yes (Y)'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:53:17

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:58:38
User entered '23 Feb 2021'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:53:17

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:58:38
User entered '13:05'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:53:17

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:25

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User entered '23 Feb 2021 13:05'	System	27 Feb 2021 16:53:17



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:01:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:58:03
User entered 'Yes (Y)'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:53:33

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:01:25

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:58:03
User entered '23 Feb 2021'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:53:33

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:01:25

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:58:03
User entered '12:54'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:53:33

**US3182292**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:01:25**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User entered '23 Feb 2021 12:54'	System	27 Feb 2021 16:53:33

US3182292

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 19:58:13
User entered 'Yes (Y)'	Jennifer Gaston (b) (4) (b) (4)	27 Feb 2021 16:53:38

**US3182292**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:01:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:03:38
User entered 'I'	System	27 Feb 2021 16:53:38

**US3182292**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:01:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:14:21
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:38:22
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	18 Mar 2021 00:44:57

US3182292

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:14:21
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:38:22
User entered '02 Mar 2021'	Cassie Uminski (b) (4)	18 Mar 2021 00:44:57



**US3182292**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:01:25**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:14:21
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:38:22
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4)	18 Mar 2021 00:44:57

US3182292

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:14:21
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:38:22
User entered empty.	Cassie Uminski (b) (4)	18 Mar 2021 00:44:57

US3182292

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:14:29
User signature succeeded.	Mary Beth Manning	18 Mar 2021 15:38:22
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	18 Mar 2021 00:45:03

**US3182292**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:01:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:49
User entered '1'	System	18 Mar 2021 00:45:03

**US3182292**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:01:25**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:49
User entered '1'	System	18 Mar 2021 00:45:03
DataPoint set to visible.	System	18 Mar 2021 00:45:03

**US3182292**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:01:25**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:14:48
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	24 Mar 2021 13:35:20

US3182292

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:14:48
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered '23 Mar 2021'	Cassie Uminski (b) (4)	24 Mar 2021 13:35:20

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Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:14:48
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	24 Mar 2021 13:35:20



**US3182292**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:01:25**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
User entered 'OLD29'	System	24 Mar 2021 13:35:20

US3182292

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4) (b) (4)	24 Mar 2021 13:36:24

US3182292

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:16:41
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	24 Mar 2021 13:36:24

US3182292

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:16:41
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered '23 Mar 2021'	Cassie Uminski (b) (4)	24 Mar 2021 13:36:24

**US3182292**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:01:25**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:16:41
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered '11:55'	(b) (4)	
	Cassie Uminski (b) (4)	24 Mar 2021 13:36:24
	(b) (4)	

**US3182292**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:01:25**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
User entered '23 Mar 2021 11:55'	System	24 Mar 2021 13:36:24

US3182292

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:16:41
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered '98.1' F	Cassie Uminski (b) (4)	24 Mar 2021 13:36:24

US3182292

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:16:41
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	24 Mar 2021 13:36:24



US3182292

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:16:41
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered empty.	Cassie Uminski (b) (4)	24 Mar 2021 13:36:24

US3182292

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:16:41
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered '66'	Cassie Uminski (b) (4)	24 Mar 2021 13:36:24

**US3182292**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:01:25**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
User entered 'bpm'	System	24 Mar 2021 13:36:24

US3182292

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:16:41
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered '16'	Cassie Uminski (b) (4)	24 Mar 2021 13:36:24

US3182292

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
User entered 'breaths/min'	System	24 Mar 2021 13:36:24

US3182292

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:16:41
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered '114'	Cassie Uminski (b) (4)	24 Mar 2021 13:36:24

**US3182292**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:01:25**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
User entered 'mmHg'	System	24 Mar 2021 13:36:24

US3182292

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:16:41
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered '72'	Cassie Uminski (b) (4)	24 Mar 2021 13:36:24



US3182292

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
User entered 'mmHg'	System	24 Mar 2021 13:36:24

US3182292

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	24 Mar 2021 13:36:24

US3182292

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:16:41
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	24 Mar 2021 13:36:24

US3182292

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:16:41
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered '23 Mar 2021'	Cassie Uminski (b) (4)	24 Mar 2021 13:36:24

**US3182292**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:01:25**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:16:41
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered '12:50'	Cassie Uminski (b) (4)	24 Mar 2021 13:36:24

**US3182292**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:01:25**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
User entered '23 Mar 2021 12:50'	System	24 Mar 2021 13:36:24

US3182292

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:16:41
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered '98.4' F	Cassie Uminski (b) (4)	24 Mar 2021 13:36:24

US3182292

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:16:41
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	24 Mar 2021 13:36:24



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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:16:41
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered empty.	Cassie Uminski (b) (4)	24 Mar 2021 13:36:24

US3182292

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:16:41
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered '64'	Cassie Uminski (b) (4)	24 Mar 2021 13:36:24

**US3182292**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:01:25**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
User entered 'bpm'	System	24 Mar 2021 13:36:24

US3182292

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:16:41
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered '16'	Cassie Uminski (b) (4)	24 Mar 2021 13:36:24

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
User entered 'breaths/min'	System	24 Mar 2021 13:36:24

US3182292

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:16:41
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered '111'	Cassie Uminski (b) (4)	24 Mar 2021 13:36:24

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
User entered 'mmHg'	System	24 Mar 2021 13:36:24

US3182292

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:16:41
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered '66'	Cassie Uminski (b) (4)	24 Mar 2021 13:36:24



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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
User entered 'mmHg'	System	24 Mar 2021 13:36:24

US3182292

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:25

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:15:12
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	24 Mar 2021 13:36:34

US3182292

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:25

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:15:12
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered '23 Mar 2021'	Cassie Uminski (b) (4)	24 Mar 2021 13:36:34

US3182292

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:15:38
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	24 Mar 2021 13:36:49

US3182292

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:15:38
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered empty.	Cassie Uminski (b) (4)	24 Mar 2021 13:36:49

US3182292

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:15:38
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered empty.	Cassie Uminski (b) (4)	24 Mar 2021 13:36:49

US3182292

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
User entered 'mRNA-1273'	System	24 Mar 2021 13:36:49
DataPoint set to visible.	System	18 Mar 2021 00:45:03

US3182292

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:15:38
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered '23 Mar 2021'	Cassie Uminski (b) (4)	24 Mar 2021 13:36:49



US3182292

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:15:38
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered '12:19'	Cassie Uminski (b) (4)	24 Mar 2021 13:36:49

**US3182292**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:01:25**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
User entered '23 Mar 2021 12:19'	System	24 Mar 2021 13:36:49

US3182292

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:15:38
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered 'Left Arm (LEFT ARM)'	Cassie Uminski (b) (4)	24 Mar 2021 13:36:49

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:15:38
User entered 'ONCE'	System	24 Mar 2021 13:36:49

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:25

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
User entered 'INTRAMUSCULAR'	System	24 Mar 2021 13:36:49

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:15:18
User signature succeeded.	Mary Beth Manning	26 Mar 2021 13:20:44
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	24 Mar 2021 13:36:53

**US3182292**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:01:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:13:53
User entered 'I'	System	24 Mar 2021 13:36:53

**US3182292**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:01:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:19:40
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:50:45
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	07 Apr 2021 15:23:58
	(b) (4)	



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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:19:40
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:50:45
	(b) (4)	
User entered '30 Mar 2021'	Cassie Uminski (b) (4)	07 Apr 2021 15:23:58
	(b) (4)	

US3182292

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:19:40
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:50:45
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4)	07 Apr 2021 15:23:58
	(b) (4)	

US3182292

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:19:40
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:50:45
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	07 Apr 2021 15:23:58
	(b) (4)	

US3182292

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:25

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:32:40
User signature succeeded.	Mary Beth Manning	07 Apr 2021 15:50:45
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	07 Apr 2021 15:24:03
	(b) (4)	

**US3182292**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:01:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 15:24:03

**US3182292**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:01:25**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	21 Apr 2021 11:55:24
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	20 Apr 2021 19:49:20
	(b) (4)	

US3182292

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	21 Apr 2021 11:55:24
	(b) (4)	
User entered '20 Apr 2021'	Cassie Uminski (b) (4)	20 Apr 2021 19:49:20
	(b) (4)	

US3182292

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:25

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	21 Apr 2021 11:55:24
	(b) (4)	
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4)	20 Apr 2021 19:49:20
	(b) (4)	



**US3182292**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:01:25**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	20 Apr 2021 19:49:20

**US3182292**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:01:25**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	21 Apr 2021 11:55:24
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	20 Apr 2021 19:49:35
	(b) (4)	

US3182292

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	21 Apr 2021 11:55:24
	(b) (4)	
User entered '20 Apr 2021'	Cassie Uminski (b) (4)	20 Apr 2021 19:49:35
	(b) (4)	

**US3182292**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:01:25**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	21 Apr 2021 11:55:24
	(b) (4)	
User entered '11:40'	Cassie Uminski (b) (4)	20 Apr 2021 19:49:35
	(b) (4)	

**US3182292**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:01:25**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '20 Apr 2021 11:40'	System	20 Apr 2021 19:49:35

US3182292

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	21 Apr 2021 11:55:24
	(b) (4)	
User entered '97.9' F	Cassie Uminski (b) (4)	20 Apr 2021 19:49:35
	(b) (4)	

US3182292

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	21 Apr 2021 11:55:24
	(b) (4)	
User entered 'Oral (Oral)'	Cassie Uminski (b) (4)	20 Apr 2021 19:49:35
	(b) (4)	

**US3182292**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:01:25**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	21 Apr 2021 11:55:24
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	20 Apr 2021 19:49:35
	(b) (4)	



US3182292

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	21 Apr 2021 11:55:24
	(b) (4)	
User entered '82'	Cassie Uminski (b) (4)	20 Apr 2021 19:49:35
	(b) (4)	

**US3182292**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:01:25**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Apr 2021 19:49:35

US3182292

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	21 Apr 2021 11:55:24
	(b) (4)	
User entered '16'	Cassie Uminski (b) (4)	20 Apr 2021 19:49:35
	(b) (4)	

**US3182292**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:01:25**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Apr 2021 19:49:35

US3182292

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	21 Apr 2021 11:55:24
	(b) (4)	
User entered '121'	Cassie Uminski (b) (4)	20 Apr 2021 19:49:35
	(b) (4)	

**US3182292**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:01:25**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Apr 2021 19:49:35

US3182292

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:25

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	21 Apr 2021 11:55:24
	(b) (4)	
User entered '75'	Cassie Uminski (b) (4)	20 Apr 2021 19:49:35
	(b) (4)	

**US3182292**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:01:25**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Apr 2021 19:49:35



**US3182292**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:01:25**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	21 Apr 2021 11:55:24
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	20 Apr 2021 19:49:47

US3182292

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:25

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	21 Apr 2021 11:55:24
	(b) (4)	
User entered '20 Apr 2021'	Cassie Uminski (b) (4)	20 Apr 2021 19:49:47
	(b) (4)	

US3182292

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:25

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	21 Apr 2021 11:55:24
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	20 Apr 2021 19:49:56

US3182292

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:25

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	21 Apr 2021 11:55:24
	(b) (4)	
User entered '20 Apr 2021'	Cassie Uminski (b) (4)	20 Apr 2021 19:49:56
	(b) (4)	

US3182292

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:25

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4) (b) (4)	21 Apr 2021 11:55:24
User entered '11:48'	Cassie Uminski (b) (4) (b) (4)	20 Apr 2021 19:49:56

**US3182292**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:01:25**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '20 Apr 2021 11:48'	System	20 Apr 2021 19:49:56

US3182292

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:01:25

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:35:36
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:28:46
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:38:27

**US3182292**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:01:25**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:07:06
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:25
User entered		
'USA-US075-2020-mRNA-1273-P301000001'	System	01 Sep 2020 18:59:59
User entered 'New'	(b) (4), (b) (6)	01 Sep 2020 18:59:59



US3182292

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User closed query 'PV Query: Please consider updating event term to COVID-19 (diagnosis).' (Site from Safety).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:42:21
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) (b) (4)	26 Oct 2020 18:56:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:56:19
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 18:07:06
Data point term sent to Coder	System	26 Oct 2020 17:51:18
Query 'PV Query: Please consider updating event term to COVID-19 (diagnosis).' answered with 'updated term' (Site from Safety).	Amy Maroun (b) (4) (b) (4)	26 Oct 2020 17:51:02
Coding entries removed.	Amy Maroun (b) (4) (b) (4)	26 Oct 2020 17:50:47
User entered 'COVID-19' reason for change: Data Entry Error	Amy Maroun (b) (4) (b) (4)	26 Oct 2020 17:50:47
User opened query 'PV Query: Please consider updating event term to COVID-19 (diagnosis).' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 15:39:28
User coded data point as SOC: Investigations, HLGT: Microbiology and serology investigations, HLT: Virus identification and serology, PT: SARS-CoV-2 test positive, LLT: COVID-19 PCR test positive - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 09:34:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 09:34:45
Data point term sent to Coder	System	01 Sep 2020 15:41:34
User entered 'Positive COVID PCR'	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:41:21

US3182292

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:07:06
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:41:21

**US3182292**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:01:25**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:07:06
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:41:21

US3182292

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:07:06
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:41:21

US3182292

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:07:06
User closed query 'PV query: Please clarify the start date of 23 Aug 2020. Was the subject experiencing signs/symptoms of COVID-19 or was this the date the test swab was collected? If experiencing symptoms, please provide. ' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 17:18:18
Query 'PV query: Please clarify the start date of 23 Aug 2020. Was the subject experiencing signs/symptoms of COVID-19 or was this the date the test swab was collected? If experiencing symptoms, please provide. ' answered with 'this is the date the subject started experiencing symptoms' (Site from Safety).	Amy Maroun (b) (4)	11 Oct 2020 14:23:19
	(b) (4)	
User opened query 'PV query: Please clarify the start date of 23 Aug 2020. Was the subject experiencing signs/symptoms of COVID-19 or was this the date the test swab was collected? If experiencing symptoms, please provide. ' (Site from Safety).	(b) (4), (b) (6)	08 Sep 2020 19:21:37
User closed query 'Per ETRTR: Please complete data entry within Illness Visit Day 1 CRF page and Saliva collection as required, thanks.' (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 18:16:30
User closed query 'Per ETRTR: Please complete data entry in Symptoms Log to reflect start date of COVID monitoring, thanks.' (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 18:16:29
Query 'Per ETRTR: Please complete data entry within Illness Visit Day 1 CRF page and Saliva collection as required, thanks.' answered with 'updated' (Site from CRA).	Amy Maroun (b) (4)	06 Sep 2020 16:45:46
	(b) (4)	
Query 'Per ETRTR: Please complete data entry in Symptoms Log to reflect start date of COVID monitoring, thanks.' answered with 'updated' (Site from CRA).	Amy Maroun (b) (4)	06 Sep 2020 16:45:40
	(b) (4)	
User opened query 'Per ETRTR: Please complete data entry within Illness Visit Day 1 CRF page and Saliva collection as required, thanks.' (Site from CRA).	(b) (4), (b) (6)	02 Sep 2020 18:02:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'Per ETRTR: Please complete data entry in Symptoms Log to reflect start date of COVID monitoring, thanks.' (Site from CRA).	(b) (4), (b) (6)	02 Sep 2020 18:02:22
User entered '23 Aug 2020'	Cassie Uminski (b) (4)	01 Sep 2020 15:41:21
	(b) (4)	

**US3182292**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:01:25**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:07:06
User entered empty.	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:41:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 15:41:21



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:07:06
User entered 'No (N)' reason for change: Data Entry Error	Amy Maroun (b) (4)	06 Sep 2020 16:47:00
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Sep 2020 15:41:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:07:06
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	06 Sep 2020 16:47:22
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	06 Sep 2020 16:47:22
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	06 Sep 2020 16:47:00
User entered '28 Aug 2020' reason for change: Data Entry Error	Amy Maroun (b) (4)	06 Sep 2020 16:47:00
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	01 Sep 2020 15:41:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:07:06
User entered empty.	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:41:21

US3182292

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV query: Please provide the stop date, when available. Please do not respond to this query until the event has ended. ' canceled (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 15:35:42
User opened query 'PV query: Please provide the stop date, when available. Please do not respond to this query until the event has ended. ' (Site from Safety).	(b) (4), (b) (6)	08 Sep 2020 19:21:59
User entered empty.	System	01 Sep 2020 15:41:21

**US3182292**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:01:25**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:07:06
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:41:21

US3182292

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:07:06
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:41:21

US3182292

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:07:06
User entered '0'	Cassie Uminski (b) (4)	01 Sep 2020 15:41:21
	(b) (4)	

US3182292

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:07:06
User entered '0'	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:41:21



US3182292

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:07:06
User entered '0'	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:41:21

US3182292

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:07:06
User entered empty.	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:41:21

US3182292

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:07:06
User entered empty.	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:41:21

US3182292

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:07:06
User entered empty.	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:41:21

US3182292

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:07:06
User entered empty.	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:41:21

US3182292

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:07:06
User entered '0'	Cassie Uminski (b) (4)	01 Sep 2020 15:41:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:07:06
User entered '0'	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:41:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:07:06
User entered '0'	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:41:21



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:07:06
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	25 Sep 2020 13:15:26
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	01 Sep 2020 15:41:21
User entered 'Not Related (NOT RELATED)'	Cassie Uminski (b) (4)	01 Sep 2020 15:41:21
	(b) (4)	

**US3182292**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:01:25**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:07:06
User entered 'Not Related (NOT RELATED)'	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:41:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:35:41
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'Please note that the query on the EOT page requested that the reason for discontinuation be updated to positive SARS COVID, which is the AE' (Site from System).	Cassie Uminski (b) (4) (b) (4)	24 Nov 2020 16:37:13
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	24 Nov 2020 16:33:18
User closed query 'Per DM CLR: Please note that Date of Dosing discontinuation is 01SEP2020 and is not within the timeframe of this AE. Review and reconcile AE and Dosing discontinuation eCRF pages as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 12:16:43
Query 'Per DM CLR: Please note that Date of Dosing discontinuation is 01SEP2020 and is not within the timeframe of this AE. Review and reconcile AE and Dosing discontinuation eCRF pages as appropriate. Otherwise, clarify.' answered with 'Per protocol, subject not eligible for second dose due to positive COVID test,' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	09 Nov 2020 20:09:21
User opened query 'Per DM CLR: Please note that Date of Dosing discontinuation is 01SEP2020 and is not within the timeframe of this AE. Review and reconcile AE and Dosing discontinuation eCRF pages as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 05:36:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 18:07:06
User closed query 'Per CDM: "Action taken with investigational product is Investigational Product Withdrawn". However Exposure form and Dosing Discontinuation form is not updated under End of study folder. Please review and update else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	17 Oct 2020 11:40:59
User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		11 Oct 2020 14:36:12
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	11 Oct 2020 14:36:12
Query 'Per CDM: "Action taken with investigational product is Investigational Product Withdrawn". However Exposure form and Dosing Discontinuation form is not updated under End of study folder. Please review and update else clarify. Thank you' answered with 'updated' (Site from DM).	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:34:34
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	11 Oct 2020 14:25:04
User opened query 'Per CDM: "Action taken with investigational product is Investigational Product Withdrawn". However Exposure form and Dosing Discontinuation form is not updated under End of study folder. Please review and update else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 04:22:04
User closed query 'Per ETRTR: Please confirm rationale for IP Withdrawn. If data entry error, please amend, thanks.' (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 18:16:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

Action taken with investigational product

Audit	User	Time (GMT)
Query 'Per ETRTR: Please confirm rationale for IP Withdrawn. If data entry error, please amend, thanks.' answered with 'per protocol to be withdrawn with diagnosis' (Site from CRA).	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:46:43
User opened query 'Per ETRTR: Please confirm rationale for IP Withdrawn. If data entry error, please amend, thanks.' (Site from CRA).	(b) (4), (b) (6)	02 Sep 2020 18:03:42
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:41:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

None

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	23 Mar 2021 03:45:33
	(b) (4)	
Signature has been broken.	Naqib Ahmad (b) (4)	18 Mar 2021 16:17:23
	(b) (4)	
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 18:07:06
User entered '0'	Cassie Uminski (b) (4)	01 Sep 2020 15:41:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:07:06
User entered 'I'	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:41:21

**US3182292**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:01:25**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:07:06
User entered '0'	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:41:21



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:07:06
User closed query 'PV query: Please provide the final outcome, when available. Please do not respond to this query until the event has ended. ' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 17:18:28
Query 'PV query: Please provide the final outcome, when available. Please do not respond to this query until the event has ended. ' answered with 'final outcome is resolved' (Site from Safety).	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:35:20
User opened query 'PV query: Please provide the final outcome, when available. Please do not respond to this query until the event has ended. ' (Site from Safety).	(b) (4), (b) (6)	08 Sep 2020 19:22:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:47:22
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:41:21

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:01:25**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:07:06
User entered empty.	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:41:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User closed query 'PV Query: Please provide the results of the immunological assessment.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:42:40
User closed query 'PV Query: (revised) Thank you for confirming the results were collected on 25 Aug 2020, please provide the date they were received.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 18:42:39
User closed query 'PV Query: Please provide the results of the saliva collected.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 18:42:30
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 18:07:06
Query 'PV Query: Please provide the results of the immunological assessment.' answered with 'These results are not available' (Site from Safety).	Amy Maroun (b) (4) (b) (4)	26 Oct 2020 18:00:18
Query 'PV Query: Please provide the results of the saliva collected.' answered with 'updated narrative with saliva results' (Site from Safety).	Amy Maroun (b) (4) (b) (4)	26 Oct 2020 17:56:30
User entered 'Days 3, 5, 7 and 9 saliva collection were positive. Days 14, 21 and 28 were negative.' reason for change: Data Entry Error	Amy Maroun (b) (4) (b) (4)	26 Oct 2020 17:56:13
Query 'PV Query: (revised) Thank you for confirming the results were collected on 25 Aug 2020, please provide the date they were received.' answered with '01SEP2020' (Site from Safety).	Amy Maroun (b) (4) (b) (4)	26 Oct 2020 17:53:13
User opened query 'PV Query: (revised) Thank you for confirming the results were collected on 25 Aug 2020, please provide the date they were received.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 15:45:06
Query 'PV Query: (revised) Thank you for confirming the results were collected on 25 Aug 2020, please provide the date they were received. PreviousPlease confirm if COVID-19 test was collected on 25 Aug 2020 or resulted on 25 Aug 2020, or if there was a test done on both the 23 Aug 2020 and 25 Aug 2020? If not drawn on 25 Aug 2020, please provide the date specimen was collected.' canceled (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 15:44:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of the immunological assessment.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 15:37:56
User opened query 'PV Query: Please provide the results of the saliva collected.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 15:37:37
User opened query 'PV Query: (revised) Thank you for confirming the results were collected on 25 Aug 2020, please provide the date they were received. PreviousPlease confirm if COVID-19 test was collected on 25 Aug 2020 or resulted on 25 Aug 2020, or if there was a test done on both the 23 Aug 2020 and 25 Aug 2020? If not drawn on 25 Aug 2020, please provide the date specimen was collected.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 15:36:46
User closed query 'PV Query: Please confirm if COVID-19 test was collected on 25 Aug 2020 or resulted on 25 Aug 2020, or if there was a test done on both the 23 Aug 2020 and 25 Aug 2020? If not drawn on 25 Aug 2020, please provide the date specimen was collected.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 17:18:40
User closed query 'PV Query: Has the subject had any known exposure to COVID-19?' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 17:18:38
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so. ' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 17:18:36
User closed query 'PV query: Please provide the signs and symptoms experienced by the subject by filling out the COVID-19 assessment tab' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 17:18:35
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so. ' answered with 'all medications taken for this event have been entered' (Site from Safety).	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:59:50

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm if COVID-19 test was collected on 25 Aug 2020 or resulted on 25 Aug 2020, or if there was a test done on both the 23 Aug 2020 and 25 Aug 2020? If not drawn on 25 Aug 2020, please provide the date specimen was collected.' answered with 'the only specimen collected was 25AUG2020 ' (Site from Safety).	Amy Maroun (b) (4)	11 Oct 2020 14:40:36
Query 'PV Query: Has the subject had any known exposure to COVID-19?' answered with 'Yes. The subject has had (b) (6) who also tested positive' (Site from Safety).	Amy Maroun (b) (4)	11 Oct 2020 14:39:50
Query 'PV query: Please provide the signs and symptoms experienced by the subject by filling out the COVID-19 assessment tab' answered with 'The assessment tab is complete with list of symptoms' (Site from Safety).	Amy Maroun (b) (4)	11 Oct 2020 14:39:00
User opened query 'PV Query: Please confirm if COVID-19 test was collected on 25 Aug 2020 or resulted on 25 Aug 2020, or if there was a test done on both the 23 Aug 2020 and 25 Aug 2020? If not drawn on 25 Aug 2020, please provide the date specimen was collected.' (Site from Safety).	(b) (4), (b) (6)	08 Sep 2020 19:24:35
User opened query 'PV Query: Has the subject had any known exposure to COVID-19?' (Site from Safety).	(b) (4), (b) (6)	08 Sep 2020 19:24:16
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so. ' (Site from Safety).	(b) (4), (b) (6)	08 Sep 2020 19:23:32
User opened query 'PV query: Please provide the signs and symptoms experienced by the subject by filling out the COVID-19 assessment tab' (Site from Safety).	(b) (4), (b) (6)	08 Sep 2020 19:22:50
Query 'Per ETRTR: COVID + Narrative should describe clinical course of events, dates, times, treatments and any other assessments which help explain the event. Please add as required, thanks.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 18:16:59

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:25

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per ETRTR: COVID + Narrative should describe clinical course of events, dates, times, treatments and any other assessments which help explain the event. Please add as required, thanks.' (Site from CRA). User entered empty.	(b) (4), (b) (6) Cassie Uminski (b) (4) (b) (4)	02 Sep 2020 18:05:45 01 Sep 2020 15:41:21

**US3182292**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:01:25**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Sep 2020 15:41:21

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:01:25**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Sep 2020 15:41:21



US3182292

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 11 Aug 2021 22:01:25**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:35:36
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:46:05
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:47:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:25

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:46:44
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 01:18:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 01:18:43
Data point term sent to Coder	System	01 Sep 2020 15:48:47
User entered 'Ibuprofen'	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:48:29

US3182292

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:25

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:46:44
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:48:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:25

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User closed query 'Per DM CLR: Please confirm if this medication is taken for Solicited Event. Note, the indication does not reflect one of the Solicited Events for the Study. Reconcile and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Oct 2020 11:43:19
Query 'Per DM CLR: Please confirm if this medication is taken for Solicited Event. Note, the indication does not reflect one of the Solicited Events for the Study. Reconcile and update as appropriate. ' answered with 'updated' (Site from DM).	Amy Maroun (b) (4) (b) (4)	10 Oct 2020 17:11:10
User opened query 'Per DM CLR: Please confirm if this medication is taken for Solicited Event. Note, the indication does not reflect one of the Solicited Events for the Study. Reconcile and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 03:51:25
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:46:44
User entered 'Positive COVID PCR'	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:48:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:25

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:29:25
DataPoint Un-verified.	Amy Maroun (b) (4)	10 Oct 2020 17:11:43
	(b) (4)	
User entered '400' reason for change: Data Entry Error	Amy Maroun (b) (4)	10 Oct 2020 17:11:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:46:44
User entered '2'	Cassie Uminski (b) (4)	01 Sep 2020 15:48:29
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:25

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Oct 2020 11:39:14
	(b) (4), (b) (6)	14 Oct 2020 14:29:26
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	Amy Maroun (b) (4) (b) (4)	10 Oct 2020 17:12:04
DataPoint Un-verified.	Amy Maroun (b) (4) (b) (4)	10 Oct 2020 17:11:43
User entered 'mg (mg)' reason for change: Data Entry Error	Amy Maroun (b) (4) (b) (4)	10 Oct 2020 17:11:43
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 03:52:17
	(b) (4), (b) (6)	04 Sep 2020 15:46:44
User entered 'tablet (TABLET)'	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:48:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:25

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:46:44
User entered empty.	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:48:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:25

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:46:44
User entered 'as needed (PRN)'	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:48:29



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:25

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:46:44
User entered empty.	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:48:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:46:44
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:48:29

US3182292

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:25

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:46:44
User entered empty.	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:48:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:46:44
User entered '26 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:48:29

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:01:25**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:46:44
User entered '0'	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:48:29

US3182292

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 14:29:16
DataPoint Un-verified.	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:42:13
User entered 'No (N)' reason for change: Data Entry Error	Amy Maroun (b) (4) (b) (4)	06 Sep 2020 16:42:13
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:46:44
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	01 Sep 2020 15:48:29

US3182292

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:25

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:29:18
DataPoint Un-verified.	Amy Maroun (b) (4)	06 Sep 2020 16:42:13
	(b) (4)	
User entered '28 Aug 2020' reason for change: Data Entry Error	Amy Maroun (b) (4)	06 Sep 2020 16:42:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:46:44
User entered empty.	Cassie Uminski (b) (4)	01 Sep 2020 15:48:29
	(b) (4)	

US3182292

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:25

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 14:29:20
DataPoint Un-verified.	Amy Maroun (b) (4)	10 Oct 2020 17:11:00
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Amy Maroun (b) (4)	10 Oct 2020 17:11:00
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Sep 2020 15:46:44
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	01 Sep 2020 15:48:29
	(b) (4)	



**US3182292**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:01:25**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 15:48:29

US3182292

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:01:25**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 15:48:29

US3182292

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:01:25**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 15:48:29

US3182292

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:01:25

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 17:42:02
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	12 Feb 2021 14:28:43

**US3182292**

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 11 Aug 2021 22:01:25**

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:55:54
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:42:51
User entered '1 Sep 2020'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:25:04

US3182292

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:01:25

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:55:54
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 14:57:28
User closed query 'Per CDM: please consider selecting 'due to SARS-CoV-2' and make all applicable updates ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 18:35:20
Query 'Per CDM: please consider selecting 'due to SARS-CoV-2' and make all applicable updates ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	24 Nov 2020 16:33:27
DataPoint Un-verified.	Cassie Uminski (b) (4) (b) (4)	24 Nov 2020 16:33:18
User entered 'Due to SARS-COV-2 (COVID)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	24 Nov 2020 16:33:18
User opened query 'Per CDM: please consider selecting 'due to SARS-CoV-2' and make all applicable updates ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 13:30:31
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 22:42:51
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:36:12
User entered 'Due to SARS-COV-2 (COVID)'	Amy Maroun (b) (4) (b) (4)	11 Oct 2020 14:25:04

US3182292

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:01:25

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:55:54
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 14:57:30
DataPoint Un-verified.	Cassie Uminski (b) (4)	24 Nov 2020 16:33:18
User entered empty; reason for change Data Entry Error	(b) (4) Cassie Uminski (b) (4)	24 Nov 2020 16:33:18
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:42:51
User entered 'Positive COVID PCR' reason for change: Data Entry Error	Amy Maroun (b) (4)	11 Oct 2020 14:36:12
User entered empty.	(b) (4) Amy Maroun (b) (4)	11 Oct 2020 14:25:04
	(b) (4)	

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered	System	01 Sep 2020 18:59:59
'USA-US075-2020-MRNA-1273-P301000001'		



**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered 'No (N)'	System	01 Sep 2020 18:59:59

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered 'No (N)'	System	01 Sep 2020 18:59:59

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered 'No (N)'	System	01 Sep 2020 18:59:59

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered 'No (N)'	System	01 Sep 2020 18:59:59

US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:01:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered 'No (N)'	System	01 Sep 2020 18:59:59

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered 'No (N)'	System	01 Sep 2020 18:59:59

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered 'No (N)'	System	01 Sep 2020 18:59:59

US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:01:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
Reviewed for Safety.	(b) (4)	27 Oct 2020 18:42:48
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Un-reviewed for Safety.	System	12 Oct 2020 17:19:01
User entered 'Mary Beth'	System	12 Oct 2020 17:19:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:18:51
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:13
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered (b) (6) '	System	01 Sep 2020 18:59:59



US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:01:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 18:42:48
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Un-reviewed for Safety.	System	12 Oct 2020 17:19:01
User entered 'Manning'	System	12 Oct 2020 17:19:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:18:51
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:13
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered (b) (6)	System	01 Sep 2020 18:59:59

US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:01:25

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:18:51
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:13
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered (b) (6)	System	01 Sep 2020 18:59:59

US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:01:25

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:18:51
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:13
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered (b) (6)	System	01 Sep 2020 18:59:59

US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:01:25

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:18:51
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:13
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered (b) (6)	System	01 Sep 2020 18:59:59

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:18:51
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:13
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered (b) (6)	System	01 Sep 2020 18:59:59

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:18:51
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:35:16
User entered 'US' (non-conformant).	System	01 Sep 2020 19:01:56

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	27 Oct 2020 18:42:57
User entered '2'	System	12 Oct 2020 17:19:01
User entered '1'	System	01 Sep 2020 19:01:56

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered	System	01 Sep 2020 18:59:59
'USA-US075-2020-MRNA-1273-P301000001'		



**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered 'No (N)'	System	01 Sep 2020 18:59:59

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered 'No (N)'	System	01 Sep 2020 18:59:59

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered 'No (N)'	System	01 Sep 2020 18:59:59

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered 'No (N)'	System	01 Sep 2020 18:59:59

US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:01:25

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered 'No (N)'	System	01 Sep 2020 18:59:59

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered 'No (N)'	System	01 Sep 2020 18:59:59

US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:01:25

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered 'No (N)'	System	01 Sep 2020 18:59:59

US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:01:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
Reviewed for Safety.	(b) (4)	27 Oct 2020 18:42:48
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Un-reviewed for Safety.	System	12 Oct 2020 17:19:01
User entered 'Mary Beth'	System	12 Oct 2020 17:19:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:18:51
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:13
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered (b) (6)	System	01 Sep 2020 18:59:59



US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:01:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 18:42:48
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Un-reviewed for Safety.	System	12 Oct 2020 17:19:01
User entered 'Manning'	System	12 Oct 2020 17:19:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:18:51
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:13
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered (b) (6)	System	01 Sep 2020 18:59:59

US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:01:25

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:18:51
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:13
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered (b) (6)	System	01 Sep 2020 18:59:59

US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:01:25

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:18:51
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:13
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered (b) (6)	System	01 Sep 2020 18:59:59

US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:01:25

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:18:51
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:13
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered (b) (6)	System	01 Sep 2020 18:59:59

US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:01:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:18:51
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:13
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered (b) (6)	System	01 Sep 2020 18:59:59

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:18:51
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:35:16
User entered 'US' (non-conformant).	System	01 Sep 2020 19:01:56

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	27 Oct 2020 18:42:57
User entered '2'	System	12 Oct 2020 17:19:01
User entered '1'	System	01 Sep 2020 19:01:56

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (1)**

**Generated On: 11 Aug 2021 22:01:25**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
User entered '01/Sep/2020 15:01'	System	01 Sep 2020 19:01:56



US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:01:25

**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.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:18:51
User entered 'I'	(b) (4), (b) (6)	01 Sep 2020 19:01:56

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered		
'USA-US075-2020-MRNA-1273-P301000001'	System	01 Sep 2020 18:59:59

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered 'No (N)'	System	01 Sep 2020 18:59:59

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered 'No (N)'	System	01 Sep 2020 18:59:59

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered 'No (N)'	System	01 Sep 2020 18:59:59

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered 'No (N)'	System	01 Sep 2020 18:59:59

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered 'No (N)'	System	01 Sep 2020 18:59:59

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered 'No (N)'	System	01 Sep 2020 18:59:59



**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered 'No (N)'	System	01 Sep 2020 18:59:59

US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:01:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
Reviewed for Safety.	(b) (4)	27 Oct 2020 18:42:48
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 18:13:39
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	12 Oct 2020 17:19:01
User entered 'Mary Beth'	System	12 Oct 2020 17:19:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:18:51
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:13
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered (b) (6)	System	01 Sep 2020 18:59:59

US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:01:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 18:42:48
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Un-reviewed for Safety.	System	12 Oct 2020 17:19:01
User entered 'Manning'	System	12 Oct 2020 17:19:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:18:51
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:13
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered (b) (6)	System	01 Sep 2020 18:59:59

US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:01:25

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:18:51
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:13
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered (b) (6)	System	01 Sep 2020 18:59:59

US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:01:25

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:18:51
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:13
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered (b) (6)	System	01 Sep 2020 18:59:59

US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:01:25

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:18:51
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:13
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered (b) (6)	System	01 Sep 2020 18:59:59

US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:01:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:18:51
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:13
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered (b) (6)	System	01 Sep 2020 18:59:59

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:18:51
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:35:16
User entered 'US' (non-conformant).	System	01 Sep 2020 19:01:56



**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	27 Oct 2020 18:42:57
User entered '2'	System	12 Oct 2020 17:19:01
User entered '1'	System	01 Sep 2020 19:01:56

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (2)**

**Generated On: 11 Aug 2021 22:01:25**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:13:39
User entered '12/Oct/2020 13:19'	System	12 Oct 2020 17:19:01

US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:01:25

**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.	Mary Beth Manning	09 Mar 2021 04:48:57
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 18:42:48
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 18:13:39
User entered 'I'	(b) (4), (b) (6)	12 Oct 2020 17:19:01

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered	System	01 Sep 2020 18:59:59
'USA-US075-2020-MRNA-1273-P301000001'		

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered 'No (N)'	System	01 Sep 2020 18:59:59

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered 'No (N)'	System	01 Sep 2020 18:59:59

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered 'No (N)'	System	01 Sep 2020 18:59:59

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered 'No (N)'	System	01 Sep 2020 18:59:59



**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered 'No (N)'	System	01 Sep 2020 18:59:59

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered 'No (N)'	System	01 Sep 2020 18:59:59

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered 'No (N)'	System	01 Sep 2020 18:59:59

US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:01:25

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
Reviewed for Safety.	(b) (4)	27 Oct 2020 18:42:48
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Un-reviewed for Safety.	System	12 Oct 2020 17:19:01
User entered 'Mary Beth'	System	12 Oct 2020 17:19:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:18:51
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:13
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered (b) (6)	System	01 Sep 2020 18:59:59

US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:01:25

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 18:42:48
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Un-reviewed for Safety.	System	12 Oct 2020 17:19:01
User entered 'Manning'	System	12 Oct 2020 17:19:01
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:18:51
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:13
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered (b) (6)	System	01 Sep 2020 18:59:59

US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:01:25

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:18:51
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:13
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered (b) (6)	System	01 Sep 2020 18:59:59

US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:01:25

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:18:51
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:13
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered (b) (6)	System	01 Sep 2020 18:59:59

US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:01:25

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:18:51
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:13
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered (b) (6)	System	01 Sep 2020 18:59:59



US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:01:25

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:18:51
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:49:13
Amendment Manager: User entered empty.	System	14 Sep 2020 21:49:13
Reviewed for Safety.	(b) (4), (b) (6)	01 Sep 2020 19:01:50
User entered (b) (6)	System	01 Sep 2020 18:59:59

US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 11 Aug 2021 22:01:25

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 18:13:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Oct 2020 17:18:51
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 06:35:16
User entered 'US' (non-conformant).	System	01 Sep 2020 19:01:56

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:01:25**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	27 Oct 2020 18:42:57
User entered '2'	System	12 Oct 2020 17:19:01
User entered '1'	System	01 Sep 2020 19:01:56

**US3182292**

**Folder: SAE USA-US075-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (3)**

**Generated On: 11 Aug 2021 22:01:25**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:41:03
User entered '27/Oct/2020 14:42'	System	27 Oct 2020 18:42:57

US3182292

Folder: SAE USA-US075-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:01:25

**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.	Mary Beth Manning	09 Mar 2021 04:48:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 20:41:03
User entered 'I'	(b) (4), (b) (6)	27 Oct 2020 18:42:57