

US3902015 (Prod: Synexus - Optimal Research - Melbourne)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:40:59

All time stamps listed in this document are displayed in GMT

US3902015

Form: Participant Creation

Data signed: (b) (4) 30 Mar 2021 18:10:33

Generated On: 12 Aug 2021 13:40:59

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[Participant ID](#)

US3902015

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

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US3902015

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 30 Mar 2021 18:10:37

Generated On: 12 Aug 2021 13:40:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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	SCRN

US3902015

Folder: Screening

Form: Demographics

Data signed: (b) (4) 30 Mar 2021 18:10:37

Generated On: 12 Aug 2021 13:40:59

Date of Birth (MMM yyyy)	(b) (6) 1966
Age	53
Age Units	YEARS
Age (Derived)	53
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
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

US3902015

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 30 Mar 2021 18:10:37

Generated On: 12 Aug 2021 13:40:59

Date of Informed Consent (*dd MMM yyyy*) 02 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input checked="" type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify \_\_\_\_\_

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number \_\_\_\_\_

Enrollment Trigger 1

US3902015

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 30 Mar 2021 18:10:37

Generated On: 12 Aug 2021 13:40:59

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3902015

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 30 Mar 2021 18:10:37

Generated On: 12 Aug 2021 13:40:59

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Were any significant conditions reported?

Yes ☒

No ☐

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US3902015

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 30 Mar 2021 18:10:37

Generated On: 12 Aug 2021 13:40:59

Condition	GENERALIZED BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	



US3902015

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 30 Mar 2021 18:10:37

Generated On: 12 Aug 2021 13:40:59

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

US3902015

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 30 Mar 2021 18:10:37

Generated On: 12 Aug 2021 13:40:59

Condition	MUSCLE SPASMS - BACK
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

US3902015

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 30 Mar 2021 18:10:37

Generated On: 12 Aug 2021 13:40:59

Condition	MORBID OBESITY
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Start Year (derived)	1996
Stop Month and Year (derived)	
Stop Year (derived)	

US3902015

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 30 Mar 2021 18:10:37

Generated On: 12 Aug 2021 13:40:59

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	10 AUG 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3902015

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 18:10:37

Generated On: 12 Aug 2021 13:40:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	02 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	09:20 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 09:20
Height ( <i>xxx.x</i> )	66 in
Weight ( <i>xxx.x</i> )	268 lb
BMI ( <i>xxx.x</i> )	43.34678 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	68 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3902015

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 30 Mar 2021 18:10:37

Generated On: 12 Aug 2021 13:40:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 SEP 2020

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

US3902015

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 30 Mar 2021 18:10:37

Generated On: 12 Aug 2021 13:40:59

Date of assessment (*dd MMM yyyy*) 02 SEP 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) 10 AUG 2019

Date of last menstruation unknown False

US3902015

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 30 Mar 2021 18:10:37

Generated On: 12 Aug 2021 13:40:59

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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**

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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



US3902015

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 30 Mar 2021 18:10:37

Generated On: 12 Aug 2021 13:40:59

<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>	

US3902015

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 30 Mar 2021 18:10:37

Generated On: 12 Aug 2021 13:40:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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	VISIT1

US3902015

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 30 Mar 2021 18:10:37

Generated On: 12 Aug 2021 13:40:59

What was the date of randomization? (dd MMM yyyy) 08 SEP 2020

What was the participant's randomization number? 145448

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 ☒

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 30 Mar 2021 18:10:37

Generated On: 12 Aug 2021 13:40:59

Height	66 in
Weight	268 lb

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 30 Mar 2021 18:10:37

Generated On: 12 Aug 2021 13:40:59

Height	66 in
Weight	268 lb
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)	08 SEP 2020
Time of assessment (00:00-23:59)	07:55 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 07:55
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 30 Mar 2021 18:10:37

Generated On: 12 Aug 2021 13:40:59

Height	66 in
Weight	268 lb
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	10:30 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 10:30
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3902015

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 30 Mar 2021 18:10:37

Generated On: 12 Aug 2021 13:40:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 SEP 2020

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

US3902015

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 30 Mar 2021 18:10:37

Generated On: 12 Aug 2021 13:40:59

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) 08 SEP 2020

What was the treatment time? (00:00-23:59) 09:58 (24 HR)

Treatment Date and Time (derived) 08 SEP 2020 09:58

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



US3902015

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Mar 2021 18:10:37

Generated On: 12 Aug 2021 13:40:59

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

Collection date (dd MMM yyyy)	8 SEP 2020
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Collection time (00:00-23:59)	09:21 (24 HR)
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Collection date and time (derived)	8 SEP 2020 09:21
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US3902015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 30 Mar 2021 18:10:37

Generated On: 12 Aug 2021 13:40:59

Collection date (dd MMM yyyy)			8 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:23	8 SEP 2020 09:23
Nasopharyngeal Swab 2	No		

US3902015

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:10:37

Generated On: 12 Aug 2021 13:40:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

**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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 10:29

PC Open Date & Time

08 SEP 2020 10:18

PC Close Date & Time

08 SEP 2020 12:48

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

**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

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

Yes ☐  
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

08 SEP 2020 13:43

PC Close Date & Time

09 SEP 2020 11:59

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:40:59

**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 ☒

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 09 SEP 2020 12:50

PC Open Date & Time 09 SEP 2020 12:00

PC Close Date & Time 10 SEP 2020 11:59

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:40:59

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:40:59

**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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 11:47

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59



US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:40:59

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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

Yes ☐

No ☒

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

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PC Time Stamp 13 SEP 2020 10:53

PC Open Date & Time 12 SEP 2020 12:00

PC Close Date & Time 13 SEP 2020 11:59

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US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:40:59

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:40:59

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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 ☒

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 SEP 2020 15:24

PC Open Date & Time 14 SEP 2020 12:00

PC Close Date & Time 15 SEP 2020 11:59

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US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 10:30

PC Open Date & Time

08 SEP 2020 10:18

PC Close Date & Time

08 SEP 2020 12:48

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

**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)**

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

08 SEP 2020 13:43

PC Close Date & Time

09 SEP 2020 11:59

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 12:51

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:40:59

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:40:59

**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

12 SEP 2020 11:48

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59



US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:40:59

**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

13 SEP 2020 10:53

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:40:59

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:40:59

**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

14 SEP 2020 15:25

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

**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 ☐

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 10:30
PC Open Date & Time	08 SEP 2020 10:18
PC Close Date & Time	08 SEP 2020 12:48

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

**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 ☐

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

08 SEP 2020 13:43

PC Close Date & Time

09 SEP 2020 11:59

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:40:59

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 ☒



US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:40:59

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 12:51
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:40:59

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)

49 of 2553

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:40:59

Yes ☐

PC Time stamp

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

51 of 2553

EAB) (1725)

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:40:59

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 11:48
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:40:59

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)

53 of 2553

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:40:59

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 10:54
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

55 of 2553



US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:40:59

Yes ☐

PC Time stamp

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:40:59

**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 ☒

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:40:59

		Yes <input type="checkbox"/>
PC Time stamp	14 SEP 2020 15:25	
PC Open Date & Time	14 SEP 2020 12:00	
PC Close Date & Time	15 SEP 2020 11:59	

US3902015

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments  
*If Contact Not Made, please provide Comments*

DAYS 1,3,5,6,7 TEMP ENTRY  
FOR DIARY NOT DONE.  
SUBJECT STATED SHE  
THOUGHT SHE ONLY HAD TO  
TAKE TEMP IF SHE HAD A  
FEVER. DAYS 1,3,6 ARE  
MISSING FOR ALL  
ASSESSMENTS. SUBJECT LIVES  
IN SINGLE FAMILY HOUSE.

US3902015

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902015

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3902015

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902015

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3902015

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902015

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 30 Mar 2021 18:10:38

Generated On: 12 Aug 2021 13:40:59

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

Visit date (dd MMM yyyy)	06 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 30 Mar 2021 18:10:38

Generated On: 12 Aug 2021 13:40:59

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)	6 OCT 2020
Time of assessment (00:00-23:59)	07:40 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 07:40
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 30 Mar 2021 18:10:38

Generated On: 12 Aug 2021 13:40:59

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	6 OCT 2020
Time of assessment (00:00-23:59)	10:38 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 10:38
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3902015

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Mar 2021 18:10:38

Generated On: 12 Aug 2021 13:40:59

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.*

US3902015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 30 Mar 2021 18:10:38

Generated On: 12 Aug 2021 13:40:59

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) 06 OCT 2020

What was the treatment time? (00:00-23:59) 10:12 (24 HR)

Treatment Date and Time (derived) 06 OCT 2020 10:12

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

US3902015

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Mar 2021 18:10:38

Generated On: 12 Aug 2021 13:40:59

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

Collection date (dd MMM yyyy)	6 OCT 2020
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Collection time (00:00-23:59)	09:27 (24 HR)
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Collection date and time (derived)	6 OCT 2020 09:27
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US3902015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 30 Mar 2021 18:10:38

Generated On: 12 Aug 2021 13:40:59

Collection date (dd MMM yyyy)			6 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:28	6 OCT 2020 09:28
Nasopharyngeal Swab 2	No		



US3902015

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:10:38

Generated On: 12 Aug 2021 13:40:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

**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

97.0 °F

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

Yes ☐  
No ☒

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

PC Time Stamp 06 OCT 2020 10:33

PC Open Date & Time 06 OCT 2020 10:32

PC Close Date & Time 06 OCT 2020 13:02

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

**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

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

Yes ☐  
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

06 OCT 2020 13:57

PC Close Date & Time

07 OCT 2020 11:59

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:40:59

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**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 22:38

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 12:18

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:40:59

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:40:59

**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

11 OCT 2020 21:55

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59



US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 15:33

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

**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

06 OCT 2020 10:33

PC Open Date & Time

06 OCT 2020 10:32

PC Close Date & Time

06 OCT 2020 13:02

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

**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)**

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

06 OCT 2020 13:57

PC Close Date & Time

07 OCT 2020 11:59

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 22:39

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:40:59

**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

08 OCT 2020 12:19

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:40:59

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:40:59

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:40:59

**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

11 OCT 2020 21:56

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59



US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:40:59

**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

12 OCT 2020 15:34

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

**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 ☐

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

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

No ☒

Yes ☐

PC Time stamp	06 OCT 2020 10:33
PC Open Date & Time	06 OCT 2020 10:32
PC Close Date & Time	06 OCT 2020 13:02

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

**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 ☐

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

06 OCT 2020 13:57

PC Close Date & Time

07 OCT 2020 11:59

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:40:59

**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 ☒

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:40:59

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 22:40
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:40:59

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)

95 of 2553



US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:40:59

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 12:19
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

97 of 2553

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:40:59

Yes ☐

PC Time stamp

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:40:59

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

99 of 2553

EAB) (1725)

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:40:59

Yes ☐

PC Time stamp

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:40:59

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 ☒

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:40:59

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 21:56
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:40:59

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 ☒



US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:40:59

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 15:34
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3902015

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3902015

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902015

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3902015

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902015

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3902015

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902015

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 30 Mar 2021 18:10:38

Generated On: 12 Aug 2021 13:40:59

Was this visit performed? Yes ☐  
No ☒

Visit date (dd MMM yyyy) \_\_\_\_\_

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

Folder OID VISIT3



US3902015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 18:10:38

Generated On: 12 Aug 2021 13:40:59

Were vital signs assessed? Yes ☐  
No ☒

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

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

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

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

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

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

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

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

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

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

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

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

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

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

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

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

US3902015

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Mar 2021 18:10:38

Generated On: 12 Aug 2021 13:40:59

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.*

US3902015

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Mar 2021 18:10:38

Generated On: 12 Aug 2021 13:40:59

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3902015

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:10:38

Generated On: 12 Aug 2021 13:40:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3902015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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 <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"/>

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

Patient Cloud Close Date & Time

19 NOV 2020 23:59



US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

TIMEPOINT	DAY 75
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"/>

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 13:55:38
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 DEC 2020 06:19:02
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 00:47:02
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 17:13:31

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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	24 DEC 2020 07:35:00
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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



**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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31 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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04 JAN 2021 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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	08 JAN 2021 06:41:34
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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	14 JAN 2021 17:04:15
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**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

23 JAN 2021 19:20:16

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

<b>TIMEPOINT</b>	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 JAN 2021 13:00:09
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 FEB 2021 11:11:08

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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	11 FEB 2021 18:22:01
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 FEB 2021 12:06:11

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59



US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**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

01 MAR 2021 19:15:42

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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 MAR 2021 11:07:49
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 07:01:01

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

<b>TIMEPOINT</b>	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 MAR 2021 21:30:55
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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 MAR 2021 06:50:38
Patient Cloud Open Date & Time	25 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**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

01 APR 2021 22:01:13

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**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

08 APR 2021 14:36:05

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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 <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	18 APR 2021 19:44:40
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59



US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**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

22 APR 2021 07:02:36

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

<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	29 APR 2021 22:56:27
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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06 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAY 2021 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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20 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2021 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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27 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2021 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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"/>

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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 <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"/>

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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10 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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14 JUN 2021 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

17 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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"/>

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**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 ☐

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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"/>

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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08 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 JUL 2021 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**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 ☐

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59



US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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"/>

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**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°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 ☐

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**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 ☐

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Close Date & Time](#)

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09 AUG 2021 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Close Date & Time](#)

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16 AUG 2021 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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="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"/>

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Close Date & Time](#)

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23 AUG 2021 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**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 ☐

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Close Date & Time](#)

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30 AUG 2021 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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02 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 SEP 2021 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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"/>

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	09 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 SEP 2021 23:59



US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

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

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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30 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 OCT 2021 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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 <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"/>

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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07 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 OCT 2021 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 404

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

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

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

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

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

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Close Date & Time](#)

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18 OCT 2021 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 411

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

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

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

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

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

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

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 ☐

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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28 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 NOV 2021 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

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

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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="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"/>

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 446

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

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

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

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

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

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	25 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 NOV 2021 23:59
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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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09 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 DEC 2021 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

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

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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30 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 JAN 2022 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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06 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 JAN 2022 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

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 ☐

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Close Date & Time](#)

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17 JAN 2022 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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20 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 JAN 2022 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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 <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"/>

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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27 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 JAN 2022 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**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°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 ☐

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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"/>

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**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 ☐

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59



US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**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 ☐

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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10 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 MAR 2022 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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 ☐

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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17 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 MAR 2022 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**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 ☐

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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31 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 APR 2022 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**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 ☐

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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07 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 APR 2022 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**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 ☐

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 APR 2022 23:59



US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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28 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 MAY 2022 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 607

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

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

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

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

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

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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"/>

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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°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"/>

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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"/>

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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"/>

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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02 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 JUN 2022 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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16 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUN 2022 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**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°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 ☐

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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23 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JUN 2022 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**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 ☐

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Close Date & Time](#)

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18 JUL 2022 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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21 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 JUL 2022 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 691

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

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

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

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

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

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

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

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**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 ☐

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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04 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 AUG 2022 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**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 ☐

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 AUG 2022 23:59



US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

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

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

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

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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25 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 AUG 2022 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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"/>

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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01 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 SEP 2022 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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"/>

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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08 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 SEP 2022 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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"/>

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 SEP 2022 23:59

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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"/>

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**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 ☐

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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29 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 OCT 2022 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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06 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 OCT 2022 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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20 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 OCT 2022 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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[Patient Cloud Open Date & Time](#)

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27 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 OCT 2022 23:59

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US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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



US3902015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:40:59

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"/>

**US3902015**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	10 NOV 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	14 NOV 2022 23:59
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US3902015

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:40:59

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		01 MAR 2021 19:15:55

US3902015

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Was Contact Attempted? Yes ☐  
No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

SUBJECT WAS IN ILLNESS  
PERIOD DURING CALL  
WINDOW

If Contact Not Made, please provide Comments

US3902015

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902015

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3902015

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902015

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3902015

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902015

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3902015

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3902015**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:40:59**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

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

Folder OID \_\_\_\_\_

US3902015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	
Time of assessment ( <i>00:00-23:59</i> )	
Vital Signs Date and Time (derived)	
Temperature ( <i>xxx.x</i> )	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse ( <i>xxx</i> )	
Pulse units	
Respiratory Rate ( <i>xxx</i> )	
Respiratory Rate units	
Systolic Blood Pressure ( <i>xxx</i> )	
Systolic Blood Pressure units	
Diastolic Blood Pressure ( <i>xxx</i> )	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3902015

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:40:59

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.*

**US3902015**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:40:59**

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

Collection date ( <i>dd MMM yyyy</i> )	_____
Collection time ( <i>00:00-23:59</i> )	_____
Collection date and time (derived)	_____

**US3902015**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:40:59**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

Date of Contact	27 OCT 2020
Time of Contact	14:00
Date and Time of Contact (derived)	27 OCT 2020 14:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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"/>

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

322 of 2553

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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"/>

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

	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 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

326 of 2553

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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"/>

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

	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 OCT 2020
------	-------------

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

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

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

Temperature	100.0 F
-------------	---------

Chills	None <input type="checkbox"/>
	Mild <input 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

330 of 2553

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

331 of 2553

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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"/>

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

	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 OCT 2020
------	-------------

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

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

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

Temperature	102.4 F
-------------	---------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

334 of 2553

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

335 of 2553



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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"/>

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

	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 OCT 2020
------	-------------

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

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

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

Temperature	100.1 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 type="checkbox"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="checkbox"/>
	Severe <input type="checkbox"/>
	Not Done <input type="checkbox"/>

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

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

338 of 2553

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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"/>

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

	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 OCT 2020
------	-------------

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

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

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

Temperature	99.7 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

342 of 2553

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

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Generated On: 12 Aug 2021 13:40:59

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

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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"/>

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	1 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

346 of 2553

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

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

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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"/>

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	2 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

350 of 2553

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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"/>

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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

Date	3 NOV 2020
------	------------

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

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

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

Temperature	101.0 F
-------------	---------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

354 of 2553

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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 ☐

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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"/>

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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

Date	4 NOV 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 type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

358 of 2553

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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 ☐

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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"/>

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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

Date	5 NOV 2020
------	------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

362 of 2553

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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"/>

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	6 NOV 2020	
Assessment Not Done	False	
O2 Saturation	92 %	
O2 Saturation Units	%	
Temperature	99.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

366 of 2553

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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 ☐

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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"/>

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	7 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

370 of 2553

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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 ☐

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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"/>

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

	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	8 NOV 2020
------	------------

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

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

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

Temperature	98.1 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

374 of 2553

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

375 of 2553



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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 ☐

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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"/>

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

	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	9 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

378 of 2553

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

379 of 2553

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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 ☐

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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"/>

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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

Date	10 NOV 2020
------	-------------

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

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

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

Temperature	97.1 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

382 of 2553

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

	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"/>



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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 ☐

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

Date of Visit	28 OCT 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	28 OCT 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

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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 6 NOV 2020

End Date 6 NOV 2020

Oxygen Saturation 92 %

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 \_\_\_\_\_

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

387 of 2553

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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[Generate Next COVID-19 Assessment](#)

Yes ☒  
No ☐

---

**US3902015**

**Folder: Illness Visit (1)**

**Form: Saliva Collection**

**Data signed:** (b) (4) 30 Mar 2021 18:10:35

**Generated On: 12 Aug 2021 13:40:59**

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	30 OCT 2020
Day 5	Yes	1 NOV 2020
Day 7	Yes	3 NOV 2020
Day 9	Yes	05 NOV 2020
Day 14	Yes	10 NOV 2020
Day 21	No	
Day 28	Yes	30 NOV 2020

US3902015

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 30 Mar 2021 18:10:35

Generated On: 12 Aug 2021 13:40:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1



US3902015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 18:10:35

Generated On: 12 Aug 2021 13:40:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 OCT 2020
Time of assessment (00:00-23:59)	15:35 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 15:35
Height (xxx.x)	66.0 in
Weight (xxx.x)	268.0 lb
Temperature (xxx.x)	100.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	95 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)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3902015

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Mar 2021 18:10:35

Generated On: 12 Aug 2021 13:40:59

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.*

US3902015

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 30 Mar 2021 18:10:35

Generated On: 12 Aug 2021 13:40:59

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

28 OCT 2020

US3902015

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3902015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 NOV 2020
Time of assessment (00:00-23:59)	13:10 (24 HR)
Vital Signs Date and Time (derived)	30 NOV 2020 13:10
Height (xxx.x)	66 in
Weight (xxx.x)	265 lb
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 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)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3902015

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 NOV 2020

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

US3902015

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

30 NOV 2020

US3902015

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

Form: Visit Date

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

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

Visit date (dd MMM yyyy)	4 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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US3902015

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

Form: Unblinding

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Date of updated informed consent ( <i>dd MMM yyyy</i> )	4 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> )	4 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3902015

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Height	66 in
Weight	270 lb
BMI (xxx.x)	43.67026

US3902015

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Height	66 in
Weight	270 lb
BMI (xxx.x)	43.67026
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)	19 FEB 2021
Time of assessment (00:00-23:59)	13:12 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 13:12
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 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)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3902015

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Height	66 in
Weight	270 lb
BMI (xxx.x)	43.67026
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)	19 FEB 2021
Time of assessment (00:00-23:59)	14:32 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 14:32
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3902015

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

Form: Physical Examination

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

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.*

US3902015

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

Form: Exposure

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

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) 19 FEB 2021

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

Treatment Date and Time (derived) 19 FEB 2021 14:00

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

US3902015

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 FEB 2021
Collection time (00:00-23:59)	12:33 (24 HR)
Collection date and time (derived)	4 FEB 2021 12:33

US3902015

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 FEB 2021
Collection time (00:00 - 23:59)	12:35
Collection Date and Time (derived)	4 FEB 2021 12:35



US3902015

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

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902015

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3902015

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

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

US3902015

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

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

Visit date (dd MMM yyyy)	16 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
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US3902015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

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)	16 MAR 2021
Time of assessment (00:00-23:59)	09:48 (24 HR)
Vital Signs Date and Time (derived)	16 MAR 2021 09:48
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3902015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	16 MAR 2021
Time of assessment (00:00-23:59)	11:38 (24 HR)
Vital Signs Date and Time (derived)	16 MAR 2021 11:38
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG

US3902015

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

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.*

US3902015

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 30 Mar 2021 18:10:35

Generated On: 12 Aug 2021 13:40:59

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) 16 MAR 2021

What was the treatment time? (00:00-23:59) 11:00 (24 HR)

Treatment Date and Time (derived) 16 MAR 2021 11:00

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



US3902015

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:10:35

Generated On: 12 Aug 2021 13:40:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902015

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3902015

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3902015

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Apr 2021 17:08:39

Generated On: 12 Aug 2021 13:40:59

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

Visit date (dd MMM yyyy)	13 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
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US3902015

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Apr 2021 17:08:39

Generated On: 12 Aug 2021 13:40:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	13 APR 2021
Time of assessment ( <i>00:00-23:59</i> )	09:20 (24 HR)
Vital Signs Date and Time (derived)	13 APR 2021 09:20
Temperature ( <i>xxx.x</i> )	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	66 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3902015

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Apr 2021 17:08:39

Generated On: 12 Aug 2021 13:40:59

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.*

US3902015

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Apr 2021 17:08:39

Generated On: 12 Aug 2021 13:40:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 APR 2021

Collection time (00:00-23:59)

09:51 (24 HR)

Collection date and time (derived)

13 APR 2021 09:51

US3902015

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 30 Mar 2021 18:10:33

Generated On: 12 Aug 2021 13:40:59

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---



US3902015

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Mar 2021 18:10:33

Generated On: 12 Aug 2021 13:40:59

AEID	USA-US210-2020-MRNA-1273-P30 1000002
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)	26 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	10 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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"/>

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424 of 2553

US3902015

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Mar 2021 18:10:33

Generated On: 12 Aug 2021 13:40:59

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 <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input 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	

US3902015

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Mar 2021 18:10:33

Generated On: 12 Aug 2021 13:40:59

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SIGNS AND SYMPTOMS:  
CHILLS, BODY ACHES,  
FATIGUE, COUGH, NASAL  
CONGESTION, MILD  
SHORTNESS OF BREATH, AND  
HEADACHE PLUS MYALGIA  
AND FEVER. INVESTIGATIONS  
AND SUPPORTING  
DIAGNOSTICS: POSTIVE  
COVID-19 PCR. DIFFERENTIAL  
DIAGNOSIS: VIRAL SYNDROME.  
COURSE OF EVENTS:  
SYMPTOMS -> TESTING -> PCP.  
TREATMENT/RESPONSE TO  
TREATMENT: NAPROXEN  
SODIUM -> PCP ONGOING.  
SUSPECTED CAUSE:  
CORONAVIRUS. OTHER  
COMMENTS: EVALUATION BY  
PCP PENDING

---

Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

---

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US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

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Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

---

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

---

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Mar 2021 18:10:33

Generated On: 12 Aug 2021 13:40:59

Name of Medication MELOXICAM

Prophylaxis Yes ☐  
No ☒

Indication BACK PAIN

Dose per administration 7.5

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☒  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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EAB) (1725)

428 of 2553

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Mar 2021 18:10:33

Generated On: 12 Aug 2021 13:40:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Mar 2021 18:10:33

Generated On: 12 Aug 2021 13:40:59

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐  
No ☒

Indication BILATERAL LOWER LEG  
SWELLING

Dose per administration 12.5

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

430 of 2553

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Mar 2021 18:10:33

Generated On: 12 Aug 2021 13:40:59

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Mar 2021 18:10:33

Generated On: 12 Aug 2021 13:40:59

Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐  
No ☒

Indication MUSCLE SPASMS IN BACK

Dose per administration 10

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

432 of 2553

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Mar 2021 18:10:33

Generated On: 12 Aug 2021 13:40:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	02 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 30 Mar 2021 18:10:33

Generated On: 12 Aug 2021 13:40:59

Name of Medication BACLOFEN

Prophylaxis Yes ☐  
No ☒

Indication MUSCLE SPASMS IN BACK

Dose per administration 5

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☒  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

434 of 2553

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 30 Mar 2021 18:10:33

Generated On: 12 Aug 2021 13:40:59

	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)		03 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 30 Mar 2021 18:10:33

Generated On: 12 Aug 2021 13:40:59

Name of Medication NAPROXEN SODIUM

Prophylaxis Yes ☐  
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 220

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

436 of 2553

EAB) (1725)

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 30 Mar 2021 18:10:33

Generated On: 12 Aug 2021 13:40:59

	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)		27 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 NOV 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"/>

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 30 Mar 2021 18:10:33

Generated On: 12 Aug 2021 13:40:59

Name of Medication THERAFLU  
[ACETAMINOPHEN/DIPHENHYD  
RAMINE HCL/PHENYLEPHRINE  
HCL]

Prophylaxis Yes ☐  
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 650/25/10

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☒

If frequency is Other, specify

EVERY 4 HOURS

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

438 of 2553

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 30 Mar 2021 18:10:33

Generated On: 12 Aug 2021 13:40:59

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	2 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	10 NOV 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"/>



US3902015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 30 Mar 2021 18:10:34

Generated On: 12 Aug 2021 13:40:59

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3902015

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:40:59

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 ☐

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

SAEID	USA-US210-2020-MRNA-1273-P301000002
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	MURRAY
Investigator's Last Name	KIMMEL
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

SAEID	USA-US210-2020-MRNA-1273-P301000002
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	MURRAY
Investigator's Last Name	KIMMEL
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)	04/NOV/2020 10:54
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

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

SAEID	USA-US210-2020-MRNA-1273-P301000002
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	MURRAY
Investigator's Last Name	KIMMEL
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/DEC/2020 15:44
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

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 30 Mar 2021 18:10:36

Generated On: 12 Aug 2021 13:40:59

SAEID	USA-US210-2020-MRNA-1273-P301000002
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	MURRAY
Investigator's Last Name	KIMMEL
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/DEC/2020 21:38
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3902015 (Prod: Synexus - Optimal Research - Melbourne)

**US3902015**

**Form: Participant Creation**

**Generated On: 12 Aug 2021 13:40:59**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'US3902015'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 14:44:45



US3902015

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:40:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	08 Sep 2020 14:07:25

US3902015

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:40:59

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '02 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 14:44:46

US3902015

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:40:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Clinic (Clinic)'	Taylor Atkinson (b) (4)	08 Sep 2020 14:07:25

US3902015

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:40:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered 'SCRN'	System	08 Sep 2020 14:07:25

US3902015

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:40:59

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered (b) (6) 1966'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 14:44:47

**US3902015**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:40:59**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '53'	Taylor Atkinson (b) (4)	04 Sep 2020 01:33:38

**US3902015**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:40:59**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered 'YEARS'	System	04 Sep 2020 01:33:38

**US3902015**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:40:59**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered '53'	System	08 Sep 2020 14:07:52



**US3902015**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:40:59**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Female (F)'	Taylor Atkinson (b) (4)	04 Sep 2020 01:33:38

**US3902015**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:40:59**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Taylor Atkinson (b) (4)	04 Sep 2020 01:33:38

**US3902015**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:40:59**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '0'	Taylor Atkinson (b) (4)	04 Sep 2020 01:33:38

**US3902015**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:40:59**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'I'	Taylor Atkinson (b) (4)	04 Sep 2020 01:33:38

**US3902015**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:40:59**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '0'	Taylor Atkinson (b) (4)	04 Sep 2020 01:33:38

US3902015

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:40:59

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '0'	Taylor Atkinson (b) (4)	04 Sep 2020 01:33:38

**US3902015**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:40:59**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '0'	Taylor Atkinson (b) (4)	04 Sep 2020 01:33:38

**US3902015**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:40:59**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '0'	Taylor Atkinson (b) (4)	04 Sep 2020 01:33:38



US3902015

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:40:59

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Taylor Atkinson (b) (4)	04 Sep 2020 01:33:38

**US3902015**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:40:59**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '0'	Taylor Atkinson (b) (4)	04 Sep 2020 01:33:38

**US3902015**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:40:59**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '0'	Taylor Atkinson (b) (4)	04 Sep 2020 01:33:38

US3902015

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:40:59

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 02-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 07:40:12
Query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 02-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.Thank you.' answered with 'Corrected' (Site from DM).	Taylor Atkinson (b) (4)	05 Nov 2020 13:18:00
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4)	05 Nov 2020 13:17:53
User opened query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 02-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 10:41:57
User entered '2 Sep 2020'	Taylor Atkinson (b) (4)	08 Sep 2020 14:07:52

**US3902015**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:40:59**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered 'Sep 2020'	System	08 Sep 2020 14:07:52

**US3902015**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:40:59**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered '2020'	System	08 Sep 2020 14:07:52

**US3902015**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:40:59**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Amendment 3 (3)'	Taylor Atkinson (b) (4)	08 Sep 2020 14:07:52

**US3902015**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:40:59**

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	08 Sep 2020 14:07:52



**US3902015**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:40:59**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Taylor Atkinson (b) (4)	08 Sep 2020 14:07:52

US3902015

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:40:59

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Taylor Atkinson (b) (4)	08 Sep 2020 14:07:52

**US3902015**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:40:59**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'No (N)'	Taylor Atkinson (b) (4)	08 Sep 2020 14:07:52

**US3902015**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:40:59**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 14:44:46

**US3902015**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:40:59**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered '1'	System	08 Sep 2020 14:07:57

US3902015

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:40:59

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	08 Sep 2020 14:07:57

US3902015

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:40:59

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	17 Sep 2020 16:42:48

US3902015

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:40:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'please confirm if back pain is area specific or generalized?' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:16:00
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 22:47:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 22:47:28
Data point term sent to Coder	System	06 Nov 2020 22:47:06
Query 'please confirm if back pain is area specific or generalized?' answered with 'Updated' (Site from CRA).	Taylor Atkinson (b) (4)	06 Nov 2020 22:46:42
Coding entries removed.	Taylor Atkinson (b) (4)	06 Nov 2020 22:46:38
User entered 'Generalized BACK PAIN' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	06 Nov 2020 22:46:38
User opened query 'please confirm if back pain is area specific or generalized?' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 14:43:14
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 16:44:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 16:44:38
Data point term sent to Coder	System	17 Sep 2020 16:43:44
User entered 'back pain'	Bram Swarr (b) (4)	17 Sep 2020 16:43:15



**US3902015**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'un UNK 2009'	Bram Swarr (b) (4)	17 Sep 2020 16:43:15

**US3902015**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '0'	Bram Swarr (b) (4)	17 Sep 2020 16:43:15

**US3902015**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	17 Sep 2020 16:43:15

**US3902015**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:40:59**

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Bram Swarr (b) (4)	17 Sep 2020 16:43:15

**US3902015**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '0'	Bram Swarr (b) (4)	17 Sep 2020 16:43:15

**US3902015**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered 'Jan 2009'	System	17 Sep 2020 16:43:15

**US3902015**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered '2009'	System	17 Sep 2020 16:43:15

**US3902015**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered empty.	System	17 Sep 2020 16:43:15



**US3902015**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered empty.	System	17 Sep 2020 16:43:15

US3902015

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:40:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'please confirm if bilateral leg swelling and if total leg or lower extremity' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:16:13
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Peripheral swelling, LLT: Swelling of legs - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 22:48:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 22:48:23
Data point term sent to Coder	System	06 Nov 2020 22:48:06
Query 'please confirm if bilateral leg swelling and if total leg or lower extremity' answered with 'Updated' (Site from CRA).	Taylor Atkinson (b) (4)	06 Nov 2020 22:47:23
Coding entries removed.	Taylor Atkinson (b) (4)	06 Nov 2020 22:47:07
User entered 'Bilateral Lower LEG SWELLING' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	06 Nov 2020 22:47:07
User opened query 'please confirm if bilateral leg swelling and if total leg or lower extremity' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:09:50
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Peripheral swelling, LLT: Unilateral leg swelling - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 16:44:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 16:44:40
Data point term sent to Coder	System	17 Sep 2020 16:43:44
User entered 'leg swelling'	Bram Swarr (b) (4)	17 Sep 2020 16:43:32

**US3902015**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'un UNK 2018'	Bram Swarr (b) (4)	17 Sep 2020 16:43:32

**US3902015**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '0'	Bram Swarr (b) (4)	17 Sep 2020 16:43:32

**US3902015**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	17 Sep 2020 16:43:32

**US3902015**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:40:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Bram Swarr (b) (4)	17 Sep 2020 16:43:32

**US3902015**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '0'	Bram Swarr (b) (4)	17 Sep 2020 16:43:32

**US3902015**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered 'Jan 2018'	System	17 Sep 2020 16:43:32



**US3902015**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered '2018'	System	17 Sep 2020 16:43:32

**US3902015**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered empty.	System	17 Sep 2020 16:43:32

**US3902015**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered empty.	System	17 Sep 2020 16:43:32

US3902015

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:40:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of MUSCLE SPASMS (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 12:39:09
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Back muscle spasms - version MedDRA\23.0.	Coder Import (b) (4)	29 Oct 2020 16:41:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Oct 2020 16:41:50
Data point term sent to Coder	System	29 Oct 2020 16:40:30
Query 'Per DM CLR: Please update the condition to include the type and/or location of MUSCLE SPASMS (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'Updated' (Site from DM).	Taylor Atkinson (b) (4)	29 Oct 2020 16:39:53
Coding entries removed.	Taylor Atkinson (b) (4)	29 Oct 2020 16:39:47
User entered 'MUSCLE SPASMS - Back' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	29 Oct 2020 16:39:47
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of MUSCLE SPASMS (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 11:50:33

US3902015

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:40:59

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Muscle spasms - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 16:45:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 16:45:36
Data point term sent to Coder	System	17 Sep 2020 16:44:45
User entered 'muscle spasms'	Bram Swarr (b) (4)	17 Sep 2020 16:43:52

**US3902015**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:40:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'un UNK 2016'	Bram Swarr (b) (4)	17 Sep 2020 16:43:52

**US3902015**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:40:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '0'	Bram Swarr (b) (4)	17 Sep 2020 16:43:52

**US3902015**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:40:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	17 Sep 2020 16:43:52



**US3902015**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:40:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Bram Swarr (b) (4)	17 Sep 2020 16:43:52

**US3902015**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:40:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '0'	Bram Swarr (b) (4)	17 Sep 2020 16:43:52

**US3902015**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:40:59**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered 'Jan 2016'	System	17 Sep 2020 16:43:52

**US3902015**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:40:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered '2016'	System	17 Sep 2020 16:43:52

**US3902015**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:40:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered empty.	System	17 Sep 2020 16:43:52

**US3902015**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:40:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered empty.	System	17 Sep 2020 16:43:52

US3902015

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:40:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Morbid obesity - version MedDRA\23.0.	Coder Import (b) (4)	17 Sep 2020 16:45:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Sep 2020 16:45:36
Data point term sent to Coder	System	17 Sep 2020 16:44:45
User entered 'morbid obesity'	Bram Swarr (b) (4)	17 Sep 2020 16:44:11

**US3902015**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:40:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'un UNK 1996'	Bram Swarr (b) (4)	17 Sep 2020 16:44:11



**US3902015**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:40:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '0'	Bram Swarr (b) (4)	17 Sep 2020 16:44:11

**US3902015**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:40:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	17 Sep 2020 16:44:11

**US3902015**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:40:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Bram Swarr (b) (4)	17 Sep 2020 16:44:11

**US3902015**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:40:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '0'	Bram Swarr (b) (4)	17 Sep 2020 16:44:11

**US3902015**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:40:59**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered 'Jan 1996'	System	17 Sep 2020 16:44:11

**US3902015**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:40:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered '1996'	System	17 Sep 2020 16:44:11

**US3902015**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:40:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered empty.	System	17 Sep 2020 16:44:11

**US3902015**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:40:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered empty.	System	17 Sep 2020 16:44:11



US3902015

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:40:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 16:45:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 16:45:36
Data point term sent to Coder	System	17 Sep 2020 16:44:47
User entered 'postmenopausal'	Bram Swarr (b) (4)	17 Sep 2020 16:44:43

US3902015

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:40:59

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '10 Aug 2019' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	06 Nov 2020 17:11:29
User entered 'un Aug 2019'	Bram Swarr (b) (4)	17 Sep 2020 16:44:43

**US3902015**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:40:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '0'	Bram Swarr (b) (4)	17 Sep 2020 16:44:43

**US3902015**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:40:59**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	17 Sep 2020 16:44:43

**US3902015**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:40:59**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Bram Swarr (b) (4)	17 Sep 2020 16:44:43

**US3902015**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:40:59**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '0'	Bram Swarr (b) (4)	17 Sep 2020 16:44:43

**US3902015**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:40:59**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered 'Aug 2019'	System	17 Sep 2020 16:44:43

**US3902015**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:40:59**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered '2019'	System	17 Sep 2020 16:44:43



**US3902015**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:40:59**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered empty.	System	17 Sep 2020 16:44:43

**US3902015**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:40:59**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered empty.	System	17 Sep 2020 16:44:43

US3902015

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	17 Sep 2020 16:34:06

US3902015

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '02 Sep 2020'	Bram Swarr (b) (4)	17 Sep 2020 16:34:06

**US3902015**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '09:20'	Bram Swarr (b) (4)	17 Sep 2020 16:34:06

**US3902015**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered '02 Sep 2020 09:20'	System	17 Sep 2020 16:34:06

US3902015

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '66' in	Bram Swarr (b) (4)	17 Sep 2020 16:34:06
DataPoint set to visible.	System	08 Sep 2020 14:07:57

US3902015

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '268' lb	Bram Swarr (b) (4)	17 Sep 2020 16:34:06
DataPoint set to visible.	System	08 Sep 2020 14:07:57



US3902015

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered '43.34678'	System	17 Sep 2020 16:34:06
DataPoint set to visible.	System	08 Sep 2020 14:07:57

**US3902015**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered 'kg/m2'	System	17 Sep 2020 16:34:06
DataPoint set to visible.	System	08 Sep 2020 14:07:57

US3902015

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'please add VS from 02Sep2020 - 97.3, 116/73, 68, and 14 to this visit. VS taken on 08Sep2020 should be captured at V1. TY?' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 18:22:04
Query 'please add VS from 02Sep2020 - 97.3, 116/73, 68, and 14 to this visit. VS taken on 08Sep2020 should be captured at V1. TY?' answered with 'Updated as appropriate' (Site from CRA).	Taylor Atkinson (b) (4)	03 Nov 2020 15:44:01
User entered '97.3' F reason for change: Data Entry Error	Taylor Atkinson (b) (4)	03 Nov 2020 15:43:45
User opened query 'please add VS from 02Sep2020 - 97.3, 116/73, 68, and 14 to this visit. VS taken on 08Sep2020 should be captured at V1. TY?' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:44:02
User closed query 'Per CDM: Screening and Day 1 were not performed on the same day, data is required for Temperature, Pulse, Respiratory Rate, Systolic Blood Pressure and Diastolic Blood Pressure. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 06:56:16
Query 'Per CDM: Screening and Day 1 were not performed on the same day, data is required for Temperature, Pulse, Respiratory Rate, Systolic Blood Pressure and Diastolic Blood Pressure. Please clarify and update as appropriate.' answered with 'data updated' (Site from DM).	Katrina Carlson (b) (4)	26 Sep 2020 15:22:32
User opened query 'Per CDM: Screening and Day 1 were not performed on the same day, data is required for Temperature, Pulse, Respiratory Rate, Systolic Blood Pressure and Diastolic Blood Pressure. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:10:56
User entered missing code ND - Not Done.	Bram Swarr (b) (4)	17 Sep 2020 16:34:06

US3902015

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'Data is required. Please provide.' (Site from System).	System	03 Nov 2020 15:44:04
Query 'Data is required. Please provide.' answered by System data change (Site from System).		03 Nov 2020 15:44:04
User entered 'Oral (Oral)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	03 Nov 2020 15:44:04
User opened query 'Data is required. Please provide.' (Site from System).	System	03 Nov 2020 15:43:45
User entered empty.	Bram Swarr (b) (4)	17 Sep 2020 16:34:06

**US3902015**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Bram Swarr (b) (4)	17 Sep 2020 16:34:06

US3902015

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '68' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	03 Nov 2020 15:43:45
User entered missing code ND - Not Done.	Bram Swarr (b) (4)	17 Sep 2020 16:34:06

**US3902015**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered 'bpm'	System	17 Sep 2020 16:34:06

US3902015

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '14' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	03 Nov 2020 15:43:45
User entered missing code ND - Not Done.	Bram Swarr (b) (4)	17 Sep 2020 16:34:06



US3902015

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered 'breaths/min'	System	17 Sep 2020 16:34:06

US3902015

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '116' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	03 Nov 2020 15:43:45
User entered missing code ND - Not Done.	Bram Swarr (b) (4)	17 Sep 2020 16:34:06

US3902015

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered 'mmHg'	System	17 Sep 2020 16:34:06

US3902015

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '73' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	03 Nov 2020 15:43:45
User entered missing code ND - Not Done.	Bram Swarr (b) (4)	17 Sep 2020 16:34:06

US3902015

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User entered 'mmHg'	System	17 Sep 2020 16:34:06

US3902015

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56

**US3902015**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56

US3902015

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:40:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	17 Sep 2020 16:36:13



**US3902015**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:40:59**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '08 Sep 2020'	Bram Swarr (b) (4)	17 Sep 2020 16:36:13

US3902015

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:40:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '02 Sep 2020'	Bram Swarr (b) (4)	17 Sep 2020 16:39:22

US3902015

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:40:59

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'No (N)'	Bram Swarr (b) (4)	17 Sep 2020 16:39:22

US3902015

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:40:59

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Bram Swarr (b) (4)	17 Sep 2020 16:39:22

US3902015

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:40:59

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Bram Swarr (b) (4)	17 Sep 2020 16:39:22

US3902015

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Bram Swarr (b) (4)	17 Sep 2020 16:39:22

**US3902015**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 12 Aug 2021 13:40:59**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '0'	Bram Swarr (b) (4)	17 Sep 2020 16:39:22

US3902015

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'Per DM CLR: Please review date of last menstruation (10 AUG 2019) as a different start date of post menopausal (UN AUG 2019) is recorded in MH. Review if dates should be reconciled. Else, provide clarification on different dates. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 07:57:16
Query 'Per DM CLR: Please review date of last menstruation (10 AUG 2019) as a different start date of post menopausal (UN AUG 2019) is recorded in MH. Review if dates should be reconciled. Else, provide clarification on different dates. ' answered with 'Corrected, entry error' (Site from DM).	Taylor Atkinson (b) (4)	06 Nov 2020 17:12:00
User opened query 'Per DM CLR: Please review date of last menstruation (10 AUG 2019) as a different start date of post menopausal (UN AUG 2019) is recorded in MH. Review if dates should be reconciled. Else, provide clarification on different dates. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 16:22:56
User entered '10 Aug 2019'	Bram Swarr (b) (4)	17 Sep 2020 16:39:22



**US3902015**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 12 Aug 2021 13:40:59**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '0'	Bram Swarr (b) (4)	17 Sep 2020 16:39:22

US3902015

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:59

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'No (N)'	Bram Swarr (b) (4)	17 Sep 2020 16:38:10

US3902015

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:59

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'No (N)'	Bram Swarr (b) (4)	17 Sep 2020 16:38:10

US3902015

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:59

**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)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'No (N)'	Bram Swarr (b) (4)	17 Sep 2020 16:38:10

US3902015

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:59

**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)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'No (N)'	Bram Swarr (b) (4)	17 Sep 2020 16:38:10

US3902015

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:59

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'No (N)'	Bram Swarr (b) (4)	17 Sep 2020 16:38:10

US3902015

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:59

[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)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'No (N)'	Bram Swarr (b) (4)	17 Sep 2020 16:38:10

US3902015

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:59

**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)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'No (N)'	Bram Swarr (b) (4)	17 Sep 2020 16:38:10



US3902015

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:59

**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)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'No (N)'	Bram Swarr (b) (4)	17 Sep 2020 16:38:10

US3902015

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:59

[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)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'No (N)'	Bram Swarr (b) (4)	17 Sep 2020 16:38:10

US3902015

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:59

**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)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'No (N)'	Bram Swarr (b) (4)	17 Sep 2020 16:38:10

US3902015

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:59

**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)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	17 Sep 2020 16:38:10

US3902015

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:59

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'No (N)'	Bram Swarr (b) (4)	17 Sep 2020 16:38:10

US3902015

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Bram Swarr (b) (4)	17 Sep 2020 16:38:10

US3902015

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:59

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '0'	Bram Swarr (b) (4)	17 Sep 2020 16:38:10

US3902015

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:59

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '0'	Bram Swarr (b) (4)	17 Sep 2020 16:38:10



US3902015

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:59

**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)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '0'	Bram Swarr (b) (4)	17 Sep 2020 16:38:10

US3902015

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:59

**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)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '0'	Bram Swarr (b) (4)	17 Sep 2020 16:38:10

US3902015

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:59

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)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '0'	Bram Swarr (b) (4)	17 Sep 2020 16:38:10

US3902015

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:59

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'I'	Bram Swarr (b) (4)	17 Sep 2020 16:38:10

US3902015

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:59

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '0'	Bram Swarr (b) (4)	17 Sep 2020 16:38:10

US3902015

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:40:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:55:56
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Bram Swarr (b) (4)	17 Sep 2020 16:38:10

**US3902015**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:40:59**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	17 Sep 2020 16:45:19

**US3902015**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:40:59**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '08 Sep 2020'	Bram Swarr (b) (4)	17 Sep 2020 16:45:19



**US3902015**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:40:59**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Clinic (Clinic)'	Bram Swarr (b) (4)	17 Sep 2020 16:45:19

**US3902015**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:40:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'VISIT1'	System	17 Sep 2020 16:45:19

US3902015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '08 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 13:04:30

US3902015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:40:59

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '145448'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 13:04:30

US3902015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:40:59

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 13:04:30

US3902015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:40:59

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)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'No (N)'	Taylor Atkinson (b) (4)	08 Sep 2020 14:08:19

US3902015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:40:59

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)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'No (N)'	Taylor Atkinson (b) (4)	08 Sep 2020 14:08:19

US3902015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:40:59

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	08 Sep 2020 14:08:19



**US3902015**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 12 Aug 2021 13:40:59**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'No (N)'	Taylor Atkinson (b) (4)	08 Sep 2020 14:08:19

US3902015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:40:59

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'No (N)'	Taylor Atkinson (b) (4)	08 Sep 2020 14:08:19

US3902015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:40:59

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'please complete' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 18:23:22
Query 'please complete' answered with 'completed' (Site from CRA).	Taylor Atkinson (b) (4)	03 Nov 2020 15:43:00
User entered 'No (N)'	Taylor Atkinson (b) (4)	03 Nov 2020 15:42:54
User opened query 'please complete' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 18:33:58
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 04:52:27
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:52:26

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:40:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'Per CDM: Screening and Day 1 were not performed on the same day. Kindly update the data for Height and Weight. Please clarify and update as appropriate. Thank you.' (Site from DM). Query 'Per CDM: Screening and Day 1 were not performed on the same day. Kindly update the data for Height and Weight. Please clarify and update as appropriate. Thank you.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 20:49:48
	Taylor Atkinson (b) (4)	06 Nov 2020 18:45:35
User entered '66' in reason for change: Data Entry Error	(b) (4)	06 Nov 2020 18:45:26
User opened query 'Per CDM: Screening and Day 1 were not performed on the same day. Kindly update the data for Height and Weight. Please clarify and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:47:36
User closed query 'Per CDM: Screening and Day 1 were not performed on the same day, data is required for Height and Weight. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 06:55:25
Query 'Per CDM: Screening and Day 1 were not performed on the same day, data is required for Height and Weight. Please clarify and update as appropriate.' answered with 'data updated' (Site from DM).	Katrina Carlson (b) (4)	26 Sep 2020 15:22:50
User opened query 'Per CDM: Screening and Day 1 were not performed on the same day, data is required for Height and Weight. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:11:59
User entered missing code ND - Not Done.	Bram Swarr (b) (4)	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:40:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '268' lb reason for change: Data Entry Error	Taylor Atkinson (b) (4)	06 Nov 2020 18:45:26
User entered missing code ND - Not Done.	Bram Swarr (b) (4)	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:40:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'Per CDM: Screening and Day 1 were not performed on the same day. Kindly update the data for Height and Weight. Please clarify and update as appropriate. Thank you.' (Site from DM). Query 'Per CDM: Screening and Day 1 were not performed on the same day. Kindly update the data for Height and Weight. Please clarify and update as appropriate. Thank you.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 20:49:48
	Taylor Atkinson (b) (4)	06 Nov 2020 18:45:35
User entered '66' in reason for change: Data Entry Error	(b) (4)	06 Nov 2020 18:45:26
User opened query 'Per CDM: Screening and Day 1 were not performed on the same day. Kindly update the data for Height and Weight. Please clarify and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:47:36
User closed query 'Per CDM: Screening and Day 1 were not performed on the same day, data is required for Height and Weight. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 06:55:25
Query 'Per CDM: Screening and Day 1 were not performed on the same day, data is required for Height and Weight. Please clarify and update as appropriate.' answered with 'data updated' (Site from DM).	Katrina Carlson (b) (4)	26 Sep 2020 15:22:50
User opened query 'Per CDM: Screening and Day 1 were not performed on the same day, data is required for Height and Weight. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:11:59
User entered missing code ND - Not Done.	Bram Swarr (b) (4)	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:40:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '268' lb reason for change: Data Entry Error	Taylor Atkinson (b) (4)	06 Nov 2020 18:45:26
User entered missing code ND - Not Done.	Bram Swarr (b) (4)	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User accepted default value 'Pre-Dose (PREDOSE)'	Bram Swarr (b) (4)	17 Sep 2020 16:47:58



US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '08 Sep 2020'	Bram Swarr (b) (4)	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '07:55'	Bram Swarr (b) (4)	17 Sep 2020 16:47:58

**US3902015**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered '08 Sep 2020 07:55'	System	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '97.9' F	Bram Swarr (b) (4)	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Oral (Oral)'	Bram Swarr (b) (4)	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Bram Swarr (b) (4)	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '64'	Bram Swarr (b) (4)	17 Sep 2020 16:47:58



US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'bpm'	System	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '16'	Bram Swarr (b) (4)	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'breaths/min'	System	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '116'	Bram Swarr (b) (4)	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'mmHg'	System	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '64'	Bram Swarr (b) (4)	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'mmHg'	System	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:40:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'Per CDM: Screening and Day 1 were not performed on the same day. Kindly update the data for Height and Weight. Please clarify and update as appropriate. Thank you.' (Site from DM). Query 'Per CDM: Screening and Day 1 were not performed on the same day. Kindly update the data for Height and Weight. Please clarify and update as appropriate. Thank you.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 20:49:48
	Taylor Atkinson (b) (4)	06 Nov 2020 18:45:35
User entered '66' in reason for change: Data Entry Error	(b) (4)	06 Nov 2020 18:45:26
User opened query 'Per CDM: Screening and Day 1 were not performed on the same day. Kindly update the data for Height and Weight. Please clarify and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:47:36
User closed query 'Per CDM: Screening and Day 1 were not performed on the same day, data is required for Height and Weight. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 06:55:25
Query 'Per CDM: Screening and Day 1 were not performed on the same day, data is required for Height and Weight. Please clarify and update as appropriate.' answered with 'data updated' (Site from DM).	Katrina Carlson (b) (4)	26 Sep 2020 15:22:50
User opened query 'Per CDM: Screening and Day 1 were not performed on the same day, data is required for Height and Weight. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 12:11:59
User entered missing code ND - Not Done.	Bram Swarr (b) (4)	17 Sep 2020 16:47:58



US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:40:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '268' lb reason for change: Data Entry Error	Taylor Atkinson (b) (4)	06 Nov 2020 18:45:26
User entered missing code ND - Not Done.	Bram Swarr (b) (4)	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User accepted default value 'Post-Dose (POSTDOSE)'	Bram Swarr (b) (4)	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '08 Sep 2020'	Bram Swarr (b) (4)	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '10:30'	Bram Swarr (b) (4)	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered '08 Sep 2020 10:30'	System	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '97.2' F	Bram Swarr (b) (4)	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Oral (Oral)'	Bram Swarr (b) (4)	17 Sep 2020 16:47:58



US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Bram Swarr (b) (4)	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '66'	Bram Swarr (b) (4)	17 Sep 2020 16:47:58

**US3902015**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'bpm'	System	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '14'	Bram Swarr (b) (4)	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'breaths/min'	System	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '135'	Bram Swarr (b) (4)	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'mmHg'	System	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '71'	Bram Swarr (b) (4)	17 Sep 2020 16:47:58



US3902015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'mmHg'	System	17 Sep 2020 16:47:58

US3902015

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:40:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	17 Sep 2020 16:45:32

US3902015

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:40:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '08 Sep 2020'	Bram Swarr (b) (4)	17 Sep 2020 16:45:32

US3902015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:40:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	08 Sep 2020 14:08:55

**US3902015**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:40:59**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Taylor Atkinson (b) (4)	08 Sep 2020 14:08:55

US3902015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:40:59

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)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Taylor Atkinson (b) (4)	08 Sep 2020 14:08:55

**US3902015**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:40:59**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 14:08:55

US3902015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:40:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'Per CDM: Date format is not correctly recorded in Treatment 1 date. Please review the Date field, it must be 2 digits (dd-MMM-yyyy) format (e.g. 01-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:48:14
Query 'Per CDM: Date format is not correctly recorded in Treatment 1 date. Please review the Date field, it must be 2 digits (dd-MMM-yyyy) format (e.g. 01-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.' answered with 'Corrected' (Site from DM).	Taylor Atkinson (b) (4)	22 Oct 2020 13:01:36
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	22 Oct 2020 13:01:28
User opened query 'Per CDM: Date format is not correctly recorded in Treatment 1 date. Please review the Date field, it must be 2 digits (dd-MMM-yyyy) format (e.g. 01-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 12:55:37
User entered '8 Sep 2020'	Taylor Atkinson (b) (4)	08 Sep 2020 14:08:55



US3902015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:40:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '09:58'	Taylor Atkinson (b) (4)	08 Sep 2020 14:08:55

**US3902015**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:40:59**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered '08 Sep 2020 09:58'	System	22 Oct 2020 13:01:28
User entered '8 Sep 2020 09:58'	System	08 Sep 2020 14:08:55

US3902015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:40:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Left Arm (LEFT ARM)'	Taylor Atkinson (b) (4)	08 Sep 2020 14:08:55

US3902015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:40:59

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'ONCE'	System	08 Sep 2020 14:08:55

US3902015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:40:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 14:08:55

US3902015

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:40:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	17 Sep 2020 16:49:50

US3902015

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:40:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '8 Sep 2020'	Bram Swarr (b) (4)	17 Sep 2020 16:49:50

**US3902015**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:40:59**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '09:21'	Bram Swarr (b) (4)	17 Sep 2020 16:49:50



**US3902015**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:40:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered '8 Sep 2020 09:21'	System	17 Sep 2020 16:49:50

US3902015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:40:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '8 Sep 2020'	Bram Swarr (b) (4)	17 Sep 2020 16:50:05

**US3902015**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Bram Swarr (b) (4)	17 Sep 2020 16:50:05

US3902015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:40:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	17 Sep 2020 16:50:05

US3902015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:40:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '09:23'	Bram Swarr (b) (4)	17 Sep 2020 16:50:05

**US3902015**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered '8 Sep 2020 09:23'	System	17 Sep 2020 16:50:05

US3902015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:40:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Bram Swarr (b) (4)	17 Sep 2020 16:50:05

US3902015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:40:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'No (N)' reason for change: Data Entry Error	Bram Swarr (b) (4)	17 Sep 2020 16:50:15
User entered 'Yes (Y)'	Bram Swarr (b) (4)	17 Sep 2020 16:50:05



US3902015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:40:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	17 Sep 2020 16:50:15
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	17 Sep 2020 16:50:15
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	17 Sep 2020 16:50:05
User entered empty.	Bram Swarr (b) (4)	17 Sep 2020 16:50:05

**US3902015**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered empty.	System	17 Sep 2020 16:50:05

US3902015

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:40:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Bram Swarr (b) (4)	17 Sep 2020 16:51:04
User entered 'No (N)'	Bram Swarr (b) (4)	17 Sep 2020 16:50:25

**US3902015**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:40:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered '1'	System	17 Sep 2020 16:51:04
User entered empty.	System	17 Sep 2020 16:50:25

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	08 Sep 2020 14:08:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-08T10:29:08', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'af855a08-387e-46d8-9219-c12d84f35303'	System	08 Sep 2020 14:29:31
User entered 'Yes (Y)'	System	08 Sep 2020 14:29:31

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-08T10:29:15', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'af855a08-387e-46d8-9219-c12d84f35303'	System	08 Sep 2020 14:29:31
User entered '97.2'	System	08 Sep 2020 14:29:31

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-08T10:29:20', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'af855a08-387e-46d8-9219-c12d84f35303'	System	08 Sep 2020 14:29:31
User entered 'No (N)'	System	08 Sep 2020 14:29:31



US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-08T10:29:27', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'af855a08-387e-46d8-9219-c12d84f35303'	System	08 Sep 2020 14:29:31
User entered '08 Sep 2020 10:29'	System	08 Sep 2020 14:29:31

**US3902015**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '08 Sep 2020 10:18'	System	08 Sep 2020 14:08:55

**US3902015**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '08 Sep 2020 12:48'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	08 Sep 2020 14:08:55
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32



US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

**US3902015**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '08 Sep 2020 13:43'	System	08 Sep 2020 14:08:55

**US3902015**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	08 Sep 2020 14:08:55
User entered 'Day 2'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-09T12:50:03', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '186c8171-69c9-4916-86dc-809439f71e10'	System	09 Sep 2020 16:50:32
User entered 'No (N)'	System	09 Sep 2020 16:50:32

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-09T12:49:05', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '186c8171-69c9-4916-86dc-809439f71e10'	System	09 Sep 2020 16:50:32
User entered 'No (N)'	System	09 Sep 2020 16:50:32

**US3902015**

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

**Form: Temperature\_Day(2)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-09T12:50:28', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '186c8171-69c9-4916-86dc-809439f71e10'	System	09 Sep 2020 16:50:32
User entered '09 Sep 2020 12:50'	System	09 Sep 2020 16:50:32



US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 14:08:55

**US3902015**

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

**Form: Temperature\_Day(2)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	08 Sep 2020 14:08:55
User entered 'Day 3'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:40:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:40:59

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32



US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 14:08:55

**US3902015**

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

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

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	08 Sep 2020 14:08:55
User entered 'Day 4'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-12T11:47:18', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '76e1a8c0-b17a-4d91-8599-7a670b326e64'	System	12 Sep 2020 16:47:54
User entered 'Yes (Y)'	System	12 Sep 2020 16:47:54

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:40:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-12T11:47:30', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '76e1a8c0-b17a-4d91-8599-7a670b326e64'	System	12 Sep 2020 16:47:54
User entered '97.3'	System	12 Sep 2020 16:47:54

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-12T11:47:33', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '76e1a8c0-b17a-4d91-8599-7a670b326e64'	System	12 Sep 2020 16:47:54
User entered 'No (N)'	System	12 Sep 2020 16:47:54

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-12T11:47:51', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '76e1a8c0-b17a-4d91-8599-7a670b326e64'	System	12 Sep 2020 16:47:54
User entered '12 Sep 2020 11:47'	System	12 Sep 2020 16:47:54



**US3902015**

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

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

**Generated On: 12 Aug 2021 13:40:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 14:08:55

**US3902015**

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

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

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	08 Sep 2020 14:08:55
User entered 'Day 5'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-13T10:53:28', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'e396cceb-020e-4453-8e7d-b18a57c36935'	System	13 Sep 2020 14:53:42
User entered 'No (N)'	System	13 Sep 2020 14:53:42

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-13T10:53:31', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'e396cceb-020e-4453-8e7d-b18a57c36935'	System	13 Sep 2020 14:53:42
User entered 'No (N)'	System	13 Sep 2020 14:53:42

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-13T10:53:35', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'e396cceb-020e-4453-8e7d-b18a57c36935'	System	13 Sep 2020 14:53:42
User entered '13 Sep 2020 10:53'	System	13 Sep 2020 14:53:42

**US3902015**

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

**Form: Temperature\_Day(5)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 14:08:55



US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	08 Sep 2020 14:08:55
User entered 'Day 6'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:40:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:40:59

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

**US3902015**

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

**Form: Temperature\_Day(6)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 14:08:55



US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	08 Sep 2020 14:08:55
User entered 'Day 7'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-14T15:24:32', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '7b750fb0-cab9-4e00-aaeb-1000fe699c79'	System	14 Sep 2020 19:24:36
User entered 'No (N)'	System	14 Sep 2020 19:24:36

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-14T15:24:27', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '7b750fb0-cab9-4e00-aaeb-1000fe699c79'	System	14 Sep 2020 19:24:36
User entered 'No (N)'	System	14 Sep 2020 19:24:36

**US3902015**

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

**Form: Temperature\_Day(7)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-14T15:24:34', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '7b750fb0-cab9-4e00-aaeb-1000fe699c79'	System	14 Sep 2020 19:24:36
User entered '14 Sep 2020 15:24'	System	14 Sep 2020 19:24:36

US3902015

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 14:08:55

**US3902015**

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

**Form: Temperature\_Day(7)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	08 Sep 2020 14:08:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 14:08:55



US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-08T10:29:38', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '989e9475-b51a-4d56-a664-6e7d8ccb5f48'	System	08 Sep 2020 14:30:12
User entered 'None (1)'	System	08 Sep 2020 14:30:12

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-08T10:29:53', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '989e9475-b51a-4d56-a664-6e7d8ccb5f48'	System	08 Sep 2020 14:30:12
User entered 'No (N)'	System	08 Sep 2020 14:30:12

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-08T10:29:57', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '989e9475-b51a-4d56-a664-6e7d8ccb5f48'	System	08 Sep 2020 14:30:12
User entered 'No (N)'	System	08 Sep 2020 14:30:12

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-08T10:30:03', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '989e9475-b51a-4d56-a664-6e7d8ccb5f48'	System	08 Sep 2020 14:30:12
User entered 'None (1)'	System	08 Sep 2020 14:30:12

**US3902015**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-08T10:30:09', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '989e9475-b51a-4d56-a664-6e7d8ccb5f48'	System	08 Sep 2020 14:30:12
User entered '08 Sep 2020 10:30'	System	08 Sep 2020 14:30:12

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '08 Sep 2020 10:18'	System	08 Sep 2020 14:08:55

**US3902015**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '08 Sep 2020 12:48'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	08 Sep 2020 14:08:55
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 14:08:55



US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32

**US3902015**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

**US3902015**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '08 Sep 2020 13:43'	System	08 Sep 2020 14:08:55



**US3902015**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	08 Sep 2020 14:08:55
User entered 'Day 2'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-09T12:50:41', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '6c956e5e-695b-464f-ae88-cb5466b79156'	System	09 Sep 2020 16:51:09
User entered 'None (1)'	System	09 Sep 2020 16:51:09

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:40:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-09T12:50:46', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '6c956e5e-695b-464f-ae88-cb5466b79156'	System	09 Sep 2020 16:51:09
User entered 'No (N)'	System	09 Sep 2020 16:51:09

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-09T12:50:50', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '6c956e5e-695b-464f-ae88-cb5466b79156'	System	09 Sep 2020 16:51:09
User entered 'No (N)'	System	09 Sep 2020 16:51:09

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-09T12:50:57', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '6c956e5e-695b-464f-ae88-cb5466b79156'	System	09 Sep 2020 16:51:09
User entered 'None (1)'	System	09 Sep 2020 16:51:09

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-09T12:51:05', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '6c956e5e-695b-464f-ae88-cb5466b79156'	System	09 Sep 2020 16:51:09
User entered '09 Sep 2020 12:51'	System	09 Sep 2020 16:51:09

**US3902015**

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

**Form: Injection Site\_Day(2)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 14:08:55



**US3902015**

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

**Form: Injection Site\_Day(2)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	08 Sep 2020 14:08:55
User entered 'Day 3'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:40:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:40:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32



**US3902015**

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

**Form: Injection Site\_Day(3)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 14:08:55

**US3902015**

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

**Form: Injection Site\_Day(3)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	08 Sep 2020 14:08:55
User entered 'Day 4'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-12T11:47:57', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '0b448851-742d-4d85-b3eb-df0848204e26'	System	12 Sep 2020 16:48:10
User entered 'None (1)'	System	12 Sep 2020 16:48:10

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:40:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-12T11:48:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '0b448851-742d-4d85-b3eb-df0848204e26'	System	12 Sep 2020 16:48:10
User entered 'No (N)'	System	12 Sep 2020 16:48:10

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-12T11:48:02', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '0b448851-742d-4d85-b3eb-df0848204e26'	System	12 Sep 2020 16:48:10
User entered 'No (N)'	System	12 Sep 2020 16:48:10

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-12T11:48:04', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '0b448851-742d-4d85-b3eb-df0848204e26'	System	12 Sep 2020 16:48:10
User entered 'None (1)'	System	12 Sep 2020 16:48:10



US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-12T11:48:06', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '0b448851-742d-4d85-b3eb-df0848204e26'	System	12 Sep 2020 16:48:10
User entered '12 Sep 2020 11:48'	System	12 Sep 2020 16:48:10

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 14:08:55

**US3902015**

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

**Form: Injection Site\_Day(4)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	08 Sep 2020 14:08:55
User entered 'Day 5'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-13T10:53:40', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'da6cee34-61c1-474a-9f9a-1a530aecf9b9'	System	13 Sep 2020 14:53:57
User entered 'None (1)'	System	13 Sep 2020 14:53:57

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-13T10:53:42', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'da6cee34-61c1-474a-9f9a-1a530aecf9b9'	System	13 Sep 2020 14:53:57
User entered 'No (N)'	System	13 Sep 2020 14:53:57

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-13T10:53:44', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'da6cee34-61c1-474a-9f9a-1a530aecf9b9'	System	13 Sep 2020 14:53:57
User entered 'No (N)'	System	13 Sep 2020 14:53:57

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-13T10:53:46', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'da6cee34-61c1-474a-9f9a-1a530aecf9b9'	System	13 Sep 2020 14:53:57
User entered 'None (1)'	System	13 Sep 2020 14:53:57



**US3902015**

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

**Form: Injection Site\_Day(5)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-13T10:53:48', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'da6cee34-61c1-474a-9f9a-1a530aecf9b9'	System	13 Sep 2020 14:53:57
User entered '13 Sep 2020 10:53'	System	13 Sep 2020 14:53:57

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 14:08:55

**US3902015**

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

**Form: Injection Site\_Day(5)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	08 Sep 2020 14:08:55
User entered 'Day 6'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:40:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32



US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:40:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32

**US3902015**

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

**Form: Injection Site\_Day(6)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 14:08:55

**US3902015**

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

**Form: Injection Site\_Day(6)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	08 Sep 2020 14:08:55
User entered 'Day 7'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-14T15:24:39', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '81073ced-b3cd-41db-bd39-9adc53e612ea'	System	14 Sep 2020 19:25:08
User entered 'None (1)'	System	14 Sep 2020 19:25:08

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-14T15:24:55', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '81073ced-b3cd-41db-bd39-9adc53e612ea'	System	14 Sep 2020 19:25:08
User entered 'No (N)'	System	14 Sep 2020 19:25:08



US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-14T15:24:58', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '81073ced-b3cd-41db-bd39-9adc53e612ea'	System	14 Sep 2020 19:25:08
User entered 'No (N)'	System	14 Sep 2020 19:25:08

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-14T15:25:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '81073ced-b3cd-41db-bd39-9adc53e612ea'	System	14 Sep 2020 19:25:08
User entered 'None (1)'	System	14 Sep 2020 19:25:08

US3902015

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-14T15:25:04', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '81073ced-b3cd-41db-bd39-9adc53e612ea'	System	14 Sep 2020 19:25:08
User entered '14 Sep 2020 15:25'	System	14 Sep 2020 19:25:08

**US3902015**

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

**Form: Injection Site\_Day(7)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 14:08:55

**US3902015**

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

**Form: Injection Site\_Day(7)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 14:08:55

**US3902015**

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

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	08 Sep 2020 14:08:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-08T10:30:14', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '5c93d682-bcc0-44a4-a1a9-621e118f844e'	System	08 Sep 2020 14:30:45
User entered 'None (0)'	System	08 Sep 2020 14:30:45

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-08T10:30:17', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '5c93d682-bcc0-44a4-a1a9-621e118f844e'	System	08 Sep 2020 14:30:45
User entered 'None (0)'	System	08 Sep 2020 14:30:45



US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-08T10:30:21', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '5c93d682-bcc0-44a4-a1a9-621e118f844e'	System	08 Sep 2020 14:30:45
User entered 'None (0)'	System	08 Sep 2020 14:30:45

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-08T10:30:24', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '5c93d682-bcc0-44a4-a1a9-621e118f844e'	System	08 Sep 2020 14:30:45
User entered 'None (0)'	System	08 Sep 2020 14:30:45

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-08T10:30:27', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '5c93d682-bcc0-44a4-a1a9-621e118f844e'	System	08 Sep 2020 14:30:45
User entered 'None (0)'	System	08 Sep 2020 14:30:45

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-08T10:30:30', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '5c93d682-bcc0-44a4-a1a9-621e118f844e'	System	08 Sep 2020 14:30:45
User entered 'None (0)'	System	08 Sep 2020 14:30:45

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-08T10:30:39', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '5c93d682-bcc0-44a4-a1a9-621e118f844e'	System	08 Sep 2020 14:30:45
User entered 'No (N)'	System	08 Sep 2020 14:30:45

**US3902015**

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

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-08T10:30:42', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '5c93d682-bcc0-44a4-a1a9-621e118f844e'	System	08 Sep 2020 14:30:45
User entered '08 Sep 2020 10:30'	System	08 Sep 2020 14:30:45

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '08 Sep 2020 10:18'	System	08 Sep 2020 14:08:55

**US3902015**

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

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '08 Sep 2020 12:48'	System	08 Sep 2020 14:08:55



US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	08 Sep 2020 14:08:55
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 14:08:55

**US3902015**

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

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:40:59**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

**US3902015**

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

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:40:59**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

**US3902015**

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

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:40:59**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32



US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '08 Sep 2020 13:43'	System	08 Sep 2020 14:08:55

**US3902015**

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

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	08 Sep 2020 14:08:55
User entered 'Day 2'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:40:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-09T12:51:12', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '2bf191a3-43cc-40b5-aec8-384309772269'	System	09 Sep 2020 16:51:47
User entered 'None (0)'	System	09 Sep 2020 16:51:47

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:40:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-09T12:51:16', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '2bf191a3-43cc-40b5-aec8-384309772269'	System	09 Sep 2020 16:51:47
User entered 'None (0)'	System	09 Sep 2020 16:51:47

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:40:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-09T12:51:19', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '2bf191a3-43cc-40b5-aec8-384309772269'	System	09 Sep 2020 16:51:47
User entered 'None (0)'	System	09 Sep 2020 16:51:47

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:40:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-09T12:51:22', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '2bf191a3-43cc-40b5-aec8-384309772269'	System	09 Sep 2020 16:51:47
User entered 'None (0)'	System	09 Sep 2020 16:51:47



US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:40:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-09T12:51:26', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '2bf191a3-43cc-40b5-aec8-384309772269'	System	09 Sep 2020 16:51:47
User entered 'None (0)'	System	09 Sep 2020 16:51:47

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:40:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-09T12:51:29', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '2bf191a3-43cc-40b5-aec8-384309772269'	System	09 Sep 2020 16:51:47
User entered 'None (0)'	System	09 Sep 2020 16:51:47

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-09T12:51:37', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '2bf191a3-43cc-40b5-aec8-384309772269'	System	09 Sep 2020 16:51:47
User entered 'No (N)'	System	09 Sep 2020 16:51:47

**US3902015**

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

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-09T12:51:40', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '2bf191a3-43cc-40b5-aec8-384309772269'	System	09 Sep 2020 16:51:47
User entered '09 Sep 2020 12:51'	System	09 Sep 2020 16:51:47

**US3902015**

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

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 14:08:55

**US3902015**

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

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	08 Sep 2020 14:08:55
User entered 'Day 3'	System	08 Sep 2020 14:08:55

**US3902015**

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

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

**Generated On: 12 Aug 2021 13:40:59**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32



**US3902015**

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

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

**Generated On: 12 Aug 2021 13:40:59**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:40:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:40:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:40:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

**US3902015**

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

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

**Generated On: 12 Aug 2021 13:40:59**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32

**US3902015**

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

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

**Generated On: 12 Aug 2021 13:40:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

**US3902015**

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

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

**Generated On: 12 Aug 2021 13:40:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 14:08:55



**US3902015**

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

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

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	08 Sep 2020 14:08:55
User entered 'Day 4'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:40:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-12T11:48:11', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '62799ed0-e1a8-43eb-b648-cfcd9deda57d'	System	12 Sep 2020 16:48:34
User entered 'None (0)'	System	12 Sep 2020 16:48:34

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:40:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-12T11:48:13', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '62799ed0-e1a8-43eb-b648-cfcd9deda57d'	System	12 Sep 2020 16:48:34
User entered 'None (0)'	System	12 Sep 2020 16:48:34

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:40:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-12T11:48:15', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '62799ed0-e1a8-43eb-b648-cfcd9deda57d'	System	12 Sep 2020 16:48:34
User entered 'None (0)'	System	12 Sep 2020 16:48:34

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:40:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-12T11:48:18', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '62799ed0-e1a8-43eb-b648-cfcd9deda57d'	System	12 Sep 2020 16:48:34
User entered 'None (0)'	System	12 Sep 2020 16:48:34

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:40:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-12T11:48:20', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '62799ed0-e1a8-43eb-b648-cfcd9deda57d'	System	12 Sep 2020 16:48:34
User entered 'None (0)'	System	12 Sep 2020 16:48:34

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:40:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-12T11:48:23', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '62799ed0-e1a8-43eb-b648-cfcd9deda57d'	System	12 Sep 2020 16:48:34
User entered 'None (0)'	System	12 Sep 2020 16:48:34



US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-12T11:48:26', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '62799ed0-e1a8-43eb-b648-cfcd9deda57d'	System	12 Sep 2020 16:48:34
User entered 'No (N)'	System	12 Sep 2020 16:48:34

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:40:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-12T11:48:28', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '62799ed0-e1a8-43eb-b648-cfcd9deda57d'	System	12 Sep 2020 16:48:34
User entered '12 Sep 2020 11:48'	System	12 Sep 2020 16:48:34

**US3902015**

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

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

**Generated On: 12 Aug 2021 13:40:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 14:08:55

**US3902015**

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

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

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	08 Sep 2020 14:08:55
User entered 'Day 5'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:40:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-13T10:53:53', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '253baee4-e013-4987-b65a-ff7d6ebb7e14'	System	13 Sep 2020 14:54:08
User entered 'None (0)'	System	13 Sep 2020 14:54:08

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:40:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-13T10:53:55', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '253baee4-e013-4987-b65a-ff7d6ebb7e14'	System	13 Sep 2020 14:54:08
User entered 'None (0)'	System	13 Sep 2020 14:54:08

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:40:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-13T10:53:56', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '253baee4-e013-4987-b65a-ff7d6ebb7e14'	System	13 Sep 2020 14:54:08
User entered 'None (0)'	System	13 Sep 2020 14:54:08



US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:40:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-13T10:53:57', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '253baee4-e013-4987-b65a-ff7d6ebb7e14'	System	13 Sep 2020 14:54:08
User entered 'None (0)'	System	13 Sep 2020 14:54:08

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:40:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-13T10:53:59', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '253baee4-e013-4987-b65a-ff7d6ebb7e14'	System	13 Sep 2020 14:54:08
User entered 'None (0)'	System	13 Sep 2020 14:54:08

**US3902015**

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

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:40:59**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-13T10:54:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '253baee4-e013-4987-b65a-ff7d6ebb7e14'	System	13 Sep 2020 14:54:08
User entered 'None (0)'	System	13 Sep 2020 14:54:08

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-13T10:54:03', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '253baee4-e013-4987-b65a-ff7d6ebb7e14'	System	13 Sep 2020 14:54:08
User entered 'No (N)'	System	13 Sep 2020 14:54:08

**US3902015**

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

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-13T10:54:05', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '253baee4-e013-4987-b65a-ff7d6ebb7e14'	System	13 Sep 2020 14:54:08
User entered '13 Sep 2020 10:54'	System	13 Sep 2020 14:54:08

**US3902015**

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

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 14:08:55

**US3902015**

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

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	08 Sep 2020 14:08:55
User entered 'Day 6'	System	08 Sep 2020 14:08:55



**US3902015**

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

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:40:59**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:40:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:40:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:40:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

**US3902015**

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

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:40:59**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

**US3902015**

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

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:40:59**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:40:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32



**US3902015**

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

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 14:08:55

**US3902015**

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

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	08 Sep 2020 14:08:55
User entered 'Day 7'	System	08 Sep 2020 14:08:55

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:40:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-14T15:25:09', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'd6f7ce99-652b-4130-b281-72c96bd2cabc'	System	14 Sep 2020 19:25:32
User entered 'None (0)'	System	14 Sep 2020 19:25:32

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:40:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-14T15:25:14', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'd6f7ce99-652b-4130-b281-72c96bd2cabc'	System	14 Sep 2020 19:25:32
User entered 'None (0)'	System	14 Sep 2020 19:25:32

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:40:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-14T15:25:16', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'd6f7ce99-652b-4130-b281-72c96bd2cabc'	System	14 Sep 2020 19:25:32
User entered 'None (0)'	System	14 Sep 2020 19:25:32

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:40:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-14T15:25:19', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'd6f7ce99-652b-4130-b281-72c96bd2cabc'	System	14 Sep 2020 19:25:32
User entered 'None (0)'	System	14 Sep 2020 19:25:32

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:40:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-14T15:25:21', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'd6f7ce99-652b-4130-b281-72c96bd2cabc'	System	14 Sep 2020 19:25:32
User entered 'None (0)'	System	14 Sep 2020 19:25:32



US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:40:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-14T15:25:23', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'd6f7ce99-652b-4130-b281-72c96bd2cabc'	System	14 Sep 2020 19:25:32
User entered 'None (0)'	System	14 Sep 2020 19:25:32

US3902015

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-14T15:25:26', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'd6f7ce99-652b-4130-b281-72c96bd2cabc'	System	14 Sep 2020 19:25:32
User entered 'No (N)'	System	14 Sep 2020 19:25:32

**US3902015**

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

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-09-14T15:25:28', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'd6f7ce99-652b-4130-b281-72c96bd2cabc'	System	14 Sep 2020 19:25:32
User entered '14 Sep 2020 15:25'	System	14 Sep 2020 19:25:32

**US3902015**

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

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 14:08:55

**US3902015**

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

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 14:08:55

**US3902015**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	17 Sep 2020 16:55:17

US3902015

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '15 Sep 2020'	Bram Swarr (b) (4)	17 Sep 2020 16:55:17

**US3902015**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Contact Made (CONTACT MADE)'	Bram Swarr (b) (4)	17 Sep 2020 16:55:17



US3902015

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Days 1,3,5,6,7 temp entry for diary not done. Subject stated she thought she only had to take temp if she had a fever. Days 1,3,6 are missing for all assessments. Subject lives in single family house.'	Bram Swarr (b) (4)	17 Sep 2020 16:55:17

US3902015

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	17 Sep 2020 16:55:52

**US3902015**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:40:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'I'	System	17 Sep 2020 16:55:52

**US3902015**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	30 Sep 2020 13:52:19

**US3902015**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '23 Sep 2020'	Bram Swarr (b) (4)	30 Sep 2020 13:52:19

**US3902015**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Contact Made (CONTACT MADE)'	Bram Swarr (b) (4)	30 Sep 2020 13:52:19

US3902015

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Bram Swarr (b) (4)	30 Sep 2020 13:52:19

**US3902015**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:40:59**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	30 Sep 2020 13:52:24



**US3902015**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:40:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'I'	System	30 Sep 2020 13:52:24

**US3902015**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	30 Sep 2020 13:52:45

US3902015

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '30 Sep 2020'	Bram Swarr (b) (4)	30 Sep 2020 13:52:45

**US3902015**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Contact Made (CONTACT MADE)'	Bram Swarr (b) (4)	30 Sep 2020 13:52:45

US3902015

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Bram Swarr (b) (4)	30 Sep 2020 13:52:45

US3902015

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	30 Sep 2020 13:52:49

**US3902015**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:40:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'I'	System	30 Sep 2020 13:52:49

**US3902015**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:40:59**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	13 Oct 2020 18:35:05



US3902015

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:40:59

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '06 Oct 2020' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	22 Oct 2020 13:00:31
Query 'Per CDM: Date format is not correctly recorded in Visit 2 Day 29 & Treatment 2 date. Please review the Date field, it must be 2 digits (dd-MMM-yyyy) format (e.g. 06-OCT-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 13:00:04
User opened query 'Per CDM: Date format is not correctly recorded in Visit 2 Day 29 & Treatment 2 date. Please review the Date field, it must be 2 digits (dd-MMM-yyyy) format (e.g. 06-OCT-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 12:59:24
User entered '6 Oct 2020'	Bram Swarr (b) (4)	13 Oct 2020 18:35:05

US3902015

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:40:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Clinic (Clinic)'	Bram Swarr (b) (4)	13 Oct 2020 18:35:05

**US3902015**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:40:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'VISIT2'	System	13 Oct 2020 18:35:05

US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User accepted default value 'Pre-Dose (PREDOSE)'	Bram Swarr (b) (4)	13 Oct 2020 18:36:38

US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	13 Oct 2020 18:36:38

US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '6 Oct 2020'	Bram Swarr (b) (4)	13 Oct 2020 18:36:38

US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '07:40'	Bram Swarr (b) (4)	13 Oct 2020 18:36:38

**US3902015**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered '6 Oct 2020 07:40'	System	13 Oct 2020 18:36:38



US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '97.4' F	Bram Swarr (b) (4)	13 Oct 2020 18:36:38

US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Oral (Oral)'	Bram Swarr (b) (4)	13 Oct 2020 18:36:38

**US3902015**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:40:59**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Bram Swarr (b) (4)	13 Oct 2020 18:36:38

US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '70'	Bram Swarr (b) (4)	13 Oct 2020 18:36:38

**US3902015**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'bpm'	System	13 Oct 2020 18:36:38

US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '16'	Bram Swarr (b) (4)	13 Oct 2020 18:36:38

US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'breaths/min'	System	13 Oct 2020 18:36:38

US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '101'	Bram Swarr (b) (4)	13 Oct 2020 18:36:38



US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'mmHg'	System	13 Oct 2020 18:36:38

US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '64'	Bram Swarr (b) (4)	13 Oct 2020 18:36:38

US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'mmHg'	System	13 Oct 2020 18:36:38

US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User accepted default value 'Post-Dose (POSTDOSE)'	Bram Swarr (b) (4)	13 Oct 2020 18:36:38

US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	13 Oct 2020 18:36:38

US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '6 Oct 2020'	Bram Swarr (b) (4)	13 Oct 2020 18:36:38

US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'Per CDM: Please clarify Time of assessment, since Exposure Time is recorded as 10:12. Per protocol section 8.2.5., post-dose vital signs should be taken at least 30 minutes after injection and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 14:21:12
Query 'Per CDM: Please clarify Time of assessment, since Exposure Time is recorded as 10:12. Per protocol section 8.2.5., post-dose vital signs should be taken at least 30 minutes after injection and update as appropriate.' answered with 'Subject refused to stay for full 30 minutes. Protocol deviation logged' (Site from DM).	Taylor Atkinson (b) (4)	22 Oct 2020 12:50:31
User opened query 'Per CDM: Please clarify Time of assessment, since Exposure Time is recorded as 10:12. Per protocol section 8.2.5., post-dose vital signs should be taken at least 30 minutes after injection and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 13:01:13
User entered '10:38'	Bram Swarr (b) (4)	13 Oct 2020 18:36:38

**US3902015**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered '6 Oct 2020 10:38'	System	13 Oct 2020 18:36:38



US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '97.0' F	Bram Swarr (b) (4)	13 Oct 2020 18:36:38

US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Oral (Oral)'	Bram Swarr (b) (4)	13 Oct 2020 18:36:38

US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Bram Swarr (b) (4)	13 Oct 2020 18:36:38

US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '65'	Bram Swarr (b) (4)	13 Oct 2020 18:36:38

US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'bpm'	System	13 Oct 2020 18:36:38

US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '16'	Bram Swarr (b) (4)	13 Oct 2020 18:36:38

US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'breaths/min'	System	13 Oct 2020 18:36:38

US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '127'	Bram Swarr (b) (4)	13 Oct 2020 18:36:38



US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'mmHg'	System	13 Oct 2020 18:36:38

US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '83'	Bram Swarr (b) (4)	13 Oct 2020 18:36:38

US3902015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'mmHg'	System	13 Oct 2020 18:36:38

US3902015

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:40:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'No (N)'	Bram Swarr (b) (4)	13 Oct 2020 18:36:48

US3902015

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:40:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Bram Swarr (b) (4)	13 Oct 2020 18:36:48

US3902015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:40:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	06 Oct 2020 14:21:14

US3902015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:40:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Taylor Atkinson (b) (4)	06 Oct 2020 14:21:14

US3902015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:40:59

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)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Taylor Atkinson (b) (4)	06 Oct 2020 14:21:14



US3902015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:40:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'MRNA-1273 OR PLACEBO'	System	06 Oct 2020 14:21:14

US3902015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:40:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'Per CDM: Date format is not correctly recorded in Visit 2 Day 29 & Treatment 2 date. Please review the Date field, it must be 2 digits (dd-MMM-yyyy) format (e.g. 06-OCT-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 08:30:14
Query 'Per CDM: Date format is not correctly recorded in Visit 2 Day 29 & Treatment 2 date. Please review the Date field, it must be 2 digits (dd-MMM-yyyy) format (e.g. 06-OCT-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.' answered with 'Updated' (Site from DM).	Taylor Atkinson (b) (4)	22 Oct 2020 13:01:06
User entered '06 Oct 2020' reason for change: Data Entry Error	(b) (4)	22 Oct 2020 13:00:43
User opened query 'Per CDM: Date format is not correctly recorded in Visit 2 Day 29 & Treatment 2 date. Please review the Date field, it must be 2 digits (dd-MMM-yyyy) format (e.g. 06-OCT-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 12:59:54
User entered '6 Oct 2020'	Taylor Atkinson (b) (4)	06 Oct 2020 14:21:14

US3902015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:40:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '10:12'	Taylor Atkinson (b) (4)	06 Oct 2020 14:21:14

**US3902015**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:40:59**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered '06 Oct 2020 10:12'	System	22 Oct 2020 13:00:43
User entered '6 Oct 2020 10:12'	System	06 Oct 2020 14:21:14

US3902015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:40:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Left Arm (LEFT ARM)'	Taylor Atkinson (b) (4)	06 Oct 2020 14:21:14

US3902015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:40:59

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'ONCE'	System	06 Oct 2020 14:21:14

US3902015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:40:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'INTRAMUSCULAR'	System	06 Oct 2020 14:21:14

US3902015

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:40:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	13 Oct 2020 18:37:05



US3902015

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:40:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '6 Oct 2020'	Bram Swarr (b) (4)	13 Oct 2020 18:37:05

**US3902015**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:40:59**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '09:27'	Bram Swarr (b) (4)	13 Oct 2020 18:37:05

**US3902015**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:40:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered '6 Oct 2020 09:27'	System	13 Oct 2020 18:37:05

US3902015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:40:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
Query 'Per GCL Lab Recon: It appears EDC has a nasopharyngeal sample with date of 06OCT2020; however, the form is not completed in GCL. Please complete.' canceled (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 18:51:13
User opened query 'Per GCL Lab Recon: It appears EDC has a nasopharyngeal sample with date of 06OCT2020; however, the form is not completed in GCL. Please complete.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 18:31:06
User entered '6 Oct 2020'	Bram Swarr (b) (4)	13 Oct 2020 18:37:18

**US3902015**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Bram Swarr (b) (4)	13 Oct 2020 18:37:18

**US3902015**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	13 Oct 2020 18:37:18

**US3902015**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '09:28'	Bram Swarr (b) (4)	13 Oct 2020 18:37:18

**US3902015**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered '6 Oct 2020 09:28'	System	13 Oct 2020 18:37:18



**US3902015**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Bram Swarr (b) (4)	13 Oct 2020 18:37:18

US3902015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:40:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'No (N)'	Bram Swarr (b) (4)	13 Oct 2020 18:37:18

**US3902015**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:40:59**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Bram Swarr (b) (4)	13 Oct 2020 18:37:18

**US3902015**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered empty.	System	13 Oct 2020 18:37:18

US3902015

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	13 Oct 2020 18:38:58

**US3902015**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:40:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered '1'	System	13 Oct 2020 18:38:58

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	06 Oct 2020 14:21:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-06T10:32:31', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '0930ef21-87ca-4c55-85f3-a6575267a089'	System	06 Oct 2020 14:33:07
User entered 'Yes (Y)'	System	06 Oct 2020 14:33:07



US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-06T10:32:48', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '0930ef21-87ca-4c55-85f3-a6575267a089'	System	06 Oct 2020 14:33:07
User entered '97.0'	System	06 Oct 2020 14:33:07

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-06T10:32:56', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '0930ef21-87ca-4c55-85f3-a6575267a089'	System	06 Oct 2020 14:33:07
User entered 'No (N)'	System	06 Oct 2020 14:33:07

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-06T10:33:03', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '0930ef21-87ca-4c55-85f3-a6575267a089'	System	06 Oct 2020 14:33:07
User entered '06 Oct 2020 10:33'	System	06 Oct 2020 14:33:07

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '06 Oct 2020 10:32'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '06 Oct 2020 13:02'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	06 Oct 2020 14:21:14
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32



US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

**US3902015**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '06 Oct 2020 13:57'	System	06 Oct 2020 14:21:14

**US3902015**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	06 Oct 2020 14:21:14
User entered 'Day 2'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-07T22:38:25', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '0c58bf3a-442f-4068-89de-0c85df3d7e2f'	System	08 Oct 2020 02:38:52
User entered 'Yes (Y)'	System	08 Oct 2020 02:38:52



US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:40:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-07T22:38:38', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '0c58bf3a-442f-4068-89de-0c85df3d7e2f'	System	08 Oct 2020 02:38:52
User entered '97.2'	System	08 Oct 2020 02:38:52

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-07T22:38:44', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '0c58bf3a-442f-4068-89de-0c85df3d7e2f'	System	08 Oct 2020 02:38:52
User entered 'No (N)'	System	08 Oct 2020 02:38:52

**US3902015**

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

**Form: Temperature\_Day(2)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-07T22:38:48', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '0c58bf3a-442f-4068-89de-0c85df3d7e2f' User entered '07 Oct 2020 22:38'	System	08 Oct 2020 02:38:52
	System	08 Oct 2020 02:38:52

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	06 Oct 2020 14:21:14
User entered 'Day 3'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-08T12:18:32', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'd8265806-122b-46aa-8c03-55029636a309'	System	08 Oct 2020 16:18:59
User entered 'Yes (Y)'	System	08 Oct 2020 16:18:59

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:40:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-08T12:18:45', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'd8265806-122b-46aa-8c03-55029636a309'	System	08 Oct 2020 16:18:59
User entered '97.3'	System	08 Oct 2020 16:18:59



US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-08T12:18:52', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'd8265806-122b-46aa-8c03-55029636a309'	System	08 Oct 2020 16:18:59
User entered 'No (N)'	System	08 Oct 2020 16:18:59

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-08T12:18:55', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'd8265806-122b-46aa-8c03-55029636a309'	System	08 Oct 2020 16:18:59
User entered '08 Oct 2020 12:18'	System	08 Oct 2020 16:18:59

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 14:21:14

**US3902015**

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

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

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	06 Oct 2020 14:21:14
User entered 'Day 4'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:40:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32



US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:40:59

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 14:21:14

**US3902015**

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

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

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	06 Oct 2020 14:21:14
User entered 'Day 5'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:40:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32



US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:40:59

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

**US3902015**

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

**Form: Temperature\_Day(5)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

**US3902015**

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

**Form: Temperature\_Day(5)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 14:21:14

**US3902015**

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

**Form: Temperature\_Day(5)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	06 Oct 2020 14:21:14
User entered 'Day 6'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-11T21:55:12', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '80485c49-5111-4967-bcae-24fad96b748c'	System	12 Oct 2020 01:55:46
User entered 'Yes (Y)'	System	12 Oct 2020 01:55:46



US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:40:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-11T21:55:35', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '80485c49-5111-4967-bcae-24fad96b748c'	System	12 Oct 2020 01:55:46
User entered '97.4'	System	12 Oct 2020 01:55:46

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-11T21:55:41', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '80485c49-5111-4967-bcae-24fad96b748c'	System	12 Oct 2020 01:55:46
User entered 'No (N)'	System	12 Oct 2020 01:55:46

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-11T21:55:44', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '80485c49-5111-4967-bcae-24fad96b748c'	System	12 Oct 2020 01:55:46
User entered '11 Oct 2020 21:55'	System	12 Oct 2020 01:55:46

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 14:21:14

**US3902015**

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

**Form: Temperature\_Day(6)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	06 Oct 2020 14:21:14
User entered 'Day 7'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-12T15:33:15', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'd22b21b1-d1b5-47d6-9d72-1e8f761d4de4'	System	12 Oct 2020 19:33:46
User entered 'Yes (Y)'	System	12 Oct 2020 19:33:46

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:40:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-12T15:33:31', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'd22b21b1-d1b5-47d6-9d72-1e8f761d4de4'	System	12 Oct 2020 19:33:46
User entered '97.2'	System	12 Oct 2020 19:33:46



US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-12T15:33:37', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'd22b21b1-d1b5-47d6-9d72-1e8f761d4de4'	System	12 Oct 2020 19:33:46
User entered 'No (N)'	System	12 Oct 2020 19:33:46

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-12T15:33:42', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'd22b21b1-d1b5-47d6-9d72-1e8f761d4de4'	System	12 Oct 2020 19:33:46
User entered '12 Oct 2020 15:33'	System	12 Oct 2020 19:33:46

**US3902015**

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

**Form: Temperature\_Day(7)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	06 Oct 2020 14:21:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-06T10:33:10', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'e6896da6-e7ca-4063-99ef-c2416e844e28'	System	06 Oct 2020 14:33:29
User entered 'None (1)'	System	06 Oct 2020 14:33:29

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-06T10:33:13', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'e6896da6-e7ca-4063-99ef-c2416e844e28'	System	06 Oct 2020 14:33:29
User entered 'No (N)'	System	06 Oct 2020 14:33:29

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-06T10:33:16', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'e6896da6-e7ca-4063-99ef-c2416e844e28'	System	06 Oct 2020 14:33:29
User entered 'No (N)'	System	06 Oct 2020 14:33:29



US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-06T10:33:19', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'e6896da6-e7ca-4063-99ef-c2416e844e28'	System	06 Oct 2020 14:33:29
User entered 'None (1)'	System	06 Oct 2020 14:33:29

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-06T10:33:23', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'e6896da6-e7ca-4063-99ef-c2416e844e28'	System	06 Oct 2020 14:33:29
User entered '06 Oct 2020 10:33'	System	06 Oct 2020 14:33:29

**US3902015**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '06 Oct 2020 10:32'	System	06 Oct 2020 14:21:14

**US3902015**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '06 Oct 2020 13:02'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	06 Oct 2020 14:21:14
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32



US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32

**US3902015**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

**US3902015**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '06 Oct 2020 13:57'	System	06 Oct 2020 14:21:14

**US3902015**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	06 Oct 2020 14:21:14
User entered 'Day 2'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-07T22:38:55', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '8fa1fe6e-b90d-45b1-bf16-899249300a31'	System	08 Oct 2020 02:39:16
User entered 'None (1)'	System	08 Oct 2020 02:39:16



US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-07T22:39:05', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '8fa1fe6e-b90d-45b1-bf16-899249300a31'	System	08 Oct 2020 02:39:16
User entered 'No (N)'	System	08 Oct 2020 02:39:16

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-07T22:39:08', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '8fa1fe6e-b90d-45b1-bf16-899249300a31'	System	08 Oct 2020 02:39:16
User entered 'No (N)'	System	08 Oct 2020 02:39:16

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-07T22:39:10', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '8fa1fe6e-b90d-45b1-bf16-899249300a31'	System	08 Oct 2020 02:39:16
User entered 'None (1)'	System	08 Oct 2020 02:39:16

**US3902015**

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

**Form: Injection Site\_Day(2)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-07T22:39:14', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '8fa1fe6e-b90d-45b1-bf16-899249300a31'	System	08 Oct 2020 02:39:16
User entered '07 Oct 2020 22:39'	System	08 Oct 2020 02:39:16

**US3902015**

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

**Form: Injection Site\_Day(2)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 14:21:14

**US3902015**

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

**Form: Injection Site\_Day(2)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	06 Oct 2020 14:21:14
User entered 'Day 3'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-08T12:19:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '835e9d01-4971-4bfd-a557-fb425d48e5c0'	System	08 Oct 2020 16:19:16
User entered 'None (1)'	System	08 Oct 2020 16:19:16



US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:40:59

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-08T12:19:02', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '835e9d01-4971-4bfd-a557-fb425d48e5c0'	System	08 Oct 2020 16:19:16
User entered 'No (N)'	System	08 Oct 2020 16:19:16

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:40:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-08T12:19:04', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '835e9d01-4971-4bfd-a557-fb425d48e5c0'	System	08 Oct 2020 16:19:16
User entered 'No (N)'	System	08 Oct 2020 16:19:16

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-08T12:19:05', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '835e9d01-4971-4bfd-a557-fb425d48e5c0'	System	08 Oct 2020 16:19:16
User entered 'None (1)'	System	08 Oct 2020 16:19:16

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-08T12:19:08', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '835e9d01-4971-4bfd-a557-fb425d48e5c0'	System	08 Oct 2020 16:19:16
User entered '08 Oct 2020 12:19'	System	08 Oct 2020 16:19:16

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 14:21:14

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	06 Oct 2020 14:21:14
User entered 'Day 4'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32



US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:40:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:40:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:40:59

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 14:21:14

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 14:21:14



US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	06 Oct 2020 14:21:14
User entered 'Day 5'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:40:59

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:40:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:40:59

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32



**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	06 Oct 2020 14:21:14
User entered 'Day 6'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-11T21:55:57', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '1a00a435-72c9-4d9e-ade3-f605d5d68cdb'	System	12 Oct 2020 01:56:10
User entered 'None (1)'	System	12 Oct 2020 01:56:10

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:40:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-11T21:55:59', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '1a00a435-72c9-4d9e-ade3-f605d5d68cdb'	System	12 Oct 2020 01:56:10
User entered 'No (N)'	System	12 Oct 2020 01:56:10

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:40:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-11T21:56:01', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '1a00a435-72c9-4d9e-ade3-f605d5d68cdb'	System	12 Oct 2020 01:56:10
User entered 'No (N)'	System	12 Oct 2020 01:56:10

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-11T21:56:03', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '1a00a435-72c9-4d9e-ade3-f605d5d68cdb'	System	12 Oct 2020 01:56:10
User entered 'None (1)'	System	12 Oct 2020 01:56:10

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-11T21:56:07', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '1a00a435-72c9-4d9e-ade3-f605d5d68cdb'	System	12 Oct 2020 01:56:10
User entered '11 Oct 2020 21:56'	System	12 Oct 2020 01:56:10



**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 14:21:14

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	06 Oct 2020 14:21:14
User entered 'Day 7'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-12T15:33:49', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '6dfe464a-f1b4-4414-ada6-0caaf27b8821'	System	12 Oct 2020 19:34:06
User entered 'None (1)'	System	12 Oct 2020 19:34:06

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:40:59

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-12T15:33:51', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '6dfe464a-f1b4-4414-ada6-0caaf27b8821'	System	12 Oct 2020 19:34:06
User entered 'No (N)'	System	12 Oct 2020 19:34:06

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:40:59

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-12T15:33:53', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '6dfe464a-f1b4-4414-ada6-0caaf27b8821'	System	12 Oct 2020 19:34:06
User entered 'No (N)'	System	12 Oct 2020 19:34:06

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-12T15:33:57', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '6dfe464a-f1b4-4414-ada6-0caaf27b8821'	System	12 Oct 2020 19:34:06
User entered 'None (1)'	System	12 Oct 2020 19:34:06

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-12T15:34:01', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '6dfe464a-f1b4-4414-ada6-0caaf27b8821'	System	12 Oct 2020 19:34:06
User entered '12 Oct 2020 15:34'	System	12 Oct 2020 19:34:06



**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	06 Oct 2020 14:21:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-06T10:33:28', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '32e056fc-5ff0-4c89-81ff-8da6eedc5498'	System	06 Oct 2020 14:34:02
User entered 'None (0)'	System	06 Oct 2020 14:34:02

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-06T10:33:31', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '32e056fc-5ff0-4c89-81ff-8da6eedc5498'	System	06 Oct 2020 14:34:02
User entered 'None (0)'	System	06 Oct 2020 14:34:02

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-06T10:33:36', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '32e056fc-5ff0-4c89-81ff-8da6eedc5498'	System	06 Oct 2020 14:34:02
User entered 'None (0)'	System	06 Oct 2020 14:34:02

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-06T10:33:39', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '32e056fc-5ff0-4c89-81ff-8da6eedc5498'	System	06 Oct 2020 14:34:02
User entered 'None (0)'	System	06 Oct 2020 14:34:02

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-06T10:33:42', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '32e056fc-5ff0-4c89-81ff-8da6eedc5498'	System	06 Oct 2020 14:34:02
User entered 'None (0)'	System	06 Oct 2020 14:34:02



US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-06T10:33:45', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '32e056fc-5ff0-4c89-81ff-8da6eedc5498'	System	06 Oct 2020 14:34:02
User entered 'None (0)'	System	06 Oct 2020 14:34:02

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-06T10:33:55', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '32e056fc-5ff0-4c89-81ff-8da6eedc5498'	System	06 Oct 2020 14:34:02
User entered 'No (N)'	System	06 Oct 2020 14:34:02

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-06T10:33:58', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '32e056fc-5ff0-4c89-81ff-8da6eedc5498'	System	06 Oct 2020 14:34:02
User entered '06 Oct 2020 10:33'	System	06 Oct 2020 14:34:02

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '06 Oct 2020 10:32'	System	06 Oct 2020 14:21:14

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '06 Oct 2020 13:02'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	06 Oct 2020 14:21:14
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 14:21:14

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:40:59**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:40:59**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32



US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:40:59**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '06 Oct 2020 13:57'	System	06 Oct 2020 14:21:14

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 14:21:14



US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	06 Oct 2020 14:21:14
User entered 'Day 2'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:40:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-07T22:39:32', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '938030a0-a609-4629-b1f9-1caf83ff664e'	System	08 Oct 2020 02:40:14
User entered 'None (0)'	System	08 Oct 2020 02:40:14

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:40:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-07T22:39:36', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '938030a0-a609-4629-b1f9-1caf83ff664e'	System	08 Oct 2020 02:40:14
User entered 'None (0)'	System	08 Oct 2020 02:40:14

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:40:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-07T22:39:42', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '938030a0-a609-4629-b1f9-1caf83ff664e'	System	08 Oct 2020 02:40:14
User entered 'None (0)'	System	08 Oct 2020 02:40:14

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:40:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-07T22:39:46', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '938030a0-a609-4629-b1f9-1caf83ff664e'	System	08 Oct 2020 02:40:14
User entered 'None (0)'	System	08 Oct 2020 02:40:14

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:40:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-07T22:39:50', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '938030a0-a609-4629-b1f9-1caf83ff664e'	System	08 Oct 2020 02:40:14
User entered 'None (0)'	System	08 Oct 2020 02:40:14

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:40:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-07T22:40:04', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '938030a0-a609-4629-b1f9-1caf83ff664e'	System	08 Oct 2020 02:40:14
User entered 'None (0)'	System	08 Oct 2020 02:40:14

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-07T22:40:08', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '938030a0-a609-4629-b1f9-1caf83ff664e'	System	08 Oct 2020 02:40:14
User entered 'No (N)'	System	08 Oct 2020 02:40:14



US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:40:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-07T22:40:11', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '938030a0-a609-4629-b1f9-1caf83ff664e'	System	08 Oct 2020 02:40:14
User entered '07 Oct 2020 22:40'	System	08 Oct 2020 02:40:14

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 14:21:14

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	06 Oct 2020 14:21:14
User entered 'Day 3'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:40:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-08T12:19:12', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'ecc24af8-98a3-48a3-ad5a-13106fef6f3a'	System	08 Oct 2020 16:19:29
User entered 'None (0)'	System	08 Oct 2020 16:19:29

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:40:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-08T12:19:14', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'ecc24af8-98a3-48a3-ad5a-13106fef6f3a'	System	08 Oct 2020 16:19:29
User entered 'None (0)'	System	08 Oct 2020 16:19:29

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:40:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-08T12:19:16', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'ecc24af8-98a3-48a3-ad5a-13106fef6f3a'	System	08 Oct 2020 16:19:29
User entered 'None (0)'	System	08 Oct 2020 16:19:29

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:40:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-08T12:19:17', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'ecc24af8-98a3-48a3-ad5a-13106fef6f3a'	System	08 Oct 2020 16:19:29
User entered 'None (0)'	System	08 Oct 2020 16:19:29



**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:40:59**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-08T12:19:18', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'ecc24af8-98a3-48a3-ad5a-13106fef6f3a'	System	08 Oct 2020 16:19:29
User entered 'None (0)'	System	08 Oct 2020 16:19:29

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:40:59**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-08T12:19:20', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'ecc24af8-98a3-48a3-ad5a-13106fef6f3a'	System	08 Oct 2020 16:19:29
User entered 'None (0)'	System	08 Oct 2020 16:19:29

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-08T12:19:22', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'ecc24af8-98a3-48a3-ad5a-13106fef6f3a'	System	08 Oct 2020 16:19:29
User entered 'No (N)'	System	08 Oct 2020 16:19:29

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-08T12:19:25', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'ecc24af8-98a3-48a3-ad5a-13106fef6f3a'	System	08 Oct 2020 16:19:29
User entered '08 Oct 2020 12:19'	System	08 Oct 2020 16:19:29

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 14:21:14

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	06 Oct 2020 14:21:14
User entered 'Day 4'	System	06 Oct 2020 14:21:14

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:40:59**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32



**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:40:59**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:40:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:40:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:40:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:40:59**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:40:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 14:21:14



**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	06 Oct 2020 14:21:14
User entered 'Day 5'	System	06 Oct 2020 14:21:14

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:40:59**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:40:59**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:40:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:40:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:40:59**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:40:59**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32



US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:40:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 14:21:14

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	06 Oct 2020 14:21:14
User entered 'Day 6'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:40:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-11T21:56:16', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '546f3f9b-55b6-48a1-b983-c1711ee7b7de'	System	12 Oct 2020 01:56:51
User entered 'None (0)'	System	12 Oct 2020 01:56:51

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:40:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-11T21:56:20', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '546f3f9b-55b6-48a1-b983-c1711ee7b7de'	System	12 Oct 2020 01:56:51
User entered 'None (0)'	System	12 Oct 2020 01:56:51

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:40:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-11T21:56:28', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '546f3f9b-55b6-48a1-b983-c1711ee7b7de'	System	12 Oct 2020 01:56:51
User entered 'None (0)'	System	12 Oct 2020 01:56:51



US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:40:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-11T21:56:34', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '546f3f9b-55b6-48a1-b983-c1711ee7b7de'	System	12 Oct 2020 01:56:51
User entered 'None (0)'	System	12 Oct 2020 01:56:51

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:40:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-11T21:56:36', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '546f3f9b-55b6-48a1-b983-c1711ee7b7de'	System	12 Oct 2020 01:56:51
User entered 'None (0)'	System	12 Oct 2020 01:56:51

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:40:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-11T21:56:39', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '546f3f9b-55b6-48a1-b983-c1711ee7b7de'	System	12 Oct 2020 01:56:51
User entered 'None (0)'	System	12 Oct 2020 01:56:51

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-11T21:56:45', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '546f3f9b-55b6-48a1-b983-c1711ee7b7de'	System	12 Oct 2020 01:56:51
User entered 'No (N)'	System	12 Oct 2020 01:56:51

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-11T21:56:47', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '546f3f9b-55b6-48a1-b983-c1711ee7b7de'	System	12 Oct 2020 01:56:51
User entered '11 Oct 2020 21:56'	System	12 Oct 2020 01:56:51

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 14:21:14

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 14:21:14

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:40:59

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
Data entry locked.	System	06 Oct 2020 14:21:14
User entered 'Day 7'	System	06 Oct 2020 14:21:14



US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:40:59

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-12T15:34:05', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'b200e523-8210-4c7f-b723-9ff8b720b2f8'	System	12 Oct 2020 19:34:28
User entered 'None (0)'	System	12 Oct 2020 19:34:28

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:40:59

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-12T15:34:06', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'b200e523-8210-4c7f-b723-9ff8b720b2f8'	System	12 Oct 2020 19:34:28
User entered 'None (0)'	System	12 Oct 2020 19:34:28

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:40:59

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-12T15:34:08', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'b200e523-8210-4c7f-b723-9ff8b720b2f8'	System	12 Oct 2020 19:34:28
User entered 'None (0)'	System	12 Oct 2020 19:34:28

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:40:59

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-12T15:34:09', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'b200e523-8210-4c7f-b723-9ff8b720b2f8'	System	12 Oct 2020 19:34:28
User entered 'None (0)'	System	12 Oct 2020 19:34:28

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:40:59

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-12T15:34:11', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'b200e523-8210-4c7f-b723-9ff8b720b2f8'	System	12 Oct 2020 19:34:28
User entered 'None (0)'	System	12 Oct 2020 19:34:28

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:40:59

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-12T15:34:13', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'b200e523-8210-4c7f-b723-9ff8b720b2f8'	System	12 Oct 2020 19:34:28
User entered 'None (0)'	System	12 Oct 2020 19:34:28

US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:40:59

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 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-12T15:34:21', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'b200e523-8210-4c7f-b723-9ff8b720b2f8'	System	12 Oct 2020 19:34:28
User entered 'No (N)'	System	12 Oct 2020 19:34:28

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-10-12T15:34:24', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'b200e523-8210-4c7f-b723-9ff8b720b2f8'	System	12 Oct 2020 19:34:28
User entered '12 Oct 2020 15:34'	System	12 Oct 2020 19:34:28



US3902015

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 14:21:14

**US3902015**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:40:59**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:56:32
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 14:21:14

**US3902015**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	13 Oct 2020 18:47:51

**US3902015**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '13 Oct 2020'	Bram Swarr (b) (4)	13 Oct 2020 18:47:51

**US3902015**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Contact Made (CONTACT MADE)'	Bram Swarr (b) (4)	13 Oct 2020 18:47:51

US3902015

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Bram Swarr (b) (4)	13 Oct 2020 18:47:51

US3902015

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	13 Oct 2020 18:47:58

**US3902015**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:40:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered '1'	System	13 Oct 2020 18:47:58



**US3902015**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 15:47:56

**US3902015**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '22 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 15:47:56

**US3902015**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Oct 2020 15:47:56

US3902015

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 15:47:56

US3902015

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 15:48:06

**US3902015**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:40:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'I'	System	23 Oct 2020 15:48:06

**US3902015**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	27 Oct 2020 20:13:26

**US3902015**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '27 Oct 2020'	Bram Swarr (b) (4)	27 Oct 2020 20:13:26



**US3902015**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Contact Made (CONTACT MADE)'	Bram Swarr (b) (4)	27 Oct 2020 20:13:26

US3902015

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Bram Swarr (b) (4)	27 Oct 2020 20:13:26

US3902015

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	27 Oct 2020 20:13:32

**US3902015**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:40:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'I'	System	27 Oct 2020 20:13:32

US3902015

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:40:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'Please confirm subject in convalescent period during study visit window.' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 17:48:27
Query 'Please confirm subject in convalescent period during study visit window.' answered with 'Confirmed' (Site from CRA).	Taylor Atkinson (b) (4)	23 Feb 2021 14:54:08
User opened query 'Please confirm subject in convalescent period during study visit window.' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 15:32:42
User entered 'No (N)'	Taylor Atkinson (b) (4)	07 Dec 2020 15:33:22

**US3902015**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:40:59**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Taylor Atkinson (b) (4)	07 Dec 2020 15:33:22

**US3902015**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:40:59**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Taylor Atkinson (b) (4)	07 Dec 2020 15:33:22

**US3902015**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:40:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'VISIT3'	System	07 Dec 2020 15:33:22



US3902015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'No (N)'	Taylor Atkinson (b) (4)	07 Dec 2020 15:33:28

US3902015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Taylor Atkinson (b) (4)	07 Dec 2020 15:33:28

**US3902015**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Taylor Atkinson (b) (4)	07 Dec 2020 15:33:28

**US3902015**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered empty.	System	07 Dec 2020 15:33:28

US3902015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Taylor Atkinson (b) (4)	07 Dec 2020 15:33:28

US3902015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Taylor Atkinson (b) (4)	07 Dec 2020 15:33:28

**US3902015**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Taylor Atkinson (b) (4)	07 Dec 2020 15:33:28

US3902015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Taylor Atkinson (b) (4)	07 Dec 2020 15:33:28



**US3902015**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered empty.	System	07 Dec 2020 15:33:28

US3902015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Taylor Atkinson (b) (4)	07 Dec 2020 15:33:28

**US3902015**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered empty.	System	07 Dec 2020 15:33:28

US3902015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Taylor Atkinson (b) (4)	07 Dec 2020 15:33:28

**US3902015**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered empty.	System	07 Dec 2020 15:33:28

US3902015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Taylor Atkinson (b) (4)	07 Dec 2020 15:33:28

**US3902015**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered empty.	System	07 Dec 2020 15:33:28

**US3902015**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06



US3902015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06

US3902015

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:40:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'No (N)'	Taylor Atkinson (b) (4)	07 Dec 2020 15:33:34

US3902015

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:40:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Taylor Atkinson (b) (4)	07 Dec 2020 15:33:34

US3902015

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:40:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'No (N)'	Taylor Atkinson (b) (4)	07 Dec 2020 15:33:50

US3902015

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:40:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Taylor Atkinson (b) (4)	07 Dec 2020 15:33:50

US3902015

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:40:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Taylor Atkinson (b) (4)	07 Dec 2020 15:33:50

US3902015

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:40:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered empty.	System	07 Dec 2020 15:33:50

US3902015

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	07 Dec 2020 15:33:54



**US3902015**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:40:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'I'	System	07 Dec 2020 15:33:54

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00
Data entry locked.	System	08 Sep 2020 14:08:55
User entered 'Day 64'	System	08 Sep 2020 14:08:55

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[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)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Have you been exposed to someone with 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)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00
Data entry locked.	System	08 Sep 2020 14:08:55
User entered '08 Nov 2020 00:01'	System	08 Sep 2020 14:08:55

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00
Data entry locked.	System	08 Sep 2020 14:08:55
User entered '12 Nov 2020 23:59'	System	08 Sep 2020 14:08:55

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00
Data entry locked.	System	08 Sep 2020 14:08:55
User entered 'Day 71'	System	08 Sep 2020 14:08:55

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[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)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Have you been exposed to someone with 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)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00
Data entry locked.	System	08 Sep 2020 14:08:55
User entered '15 Nov 2020 00:01'	System	08 Sep 2020 14:08:55



**US3902015**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:33:00
Data entry locked.	System	08 Sep 2020 14:08:55
User entered '19 Nov 2020 23:59'	System	08 Sep 2020 14:08:55

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[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 (1e820764c1ba5f94)', Time: '2020-11-30T13:55:29', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '9c11f119-1700-4c76-8bcb-1a6dec1d8866'	System	30 Nov 2020 18:55:41
User entered 'No (N)'	System	30 Nov 2020 18:55:41

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Have you been exposed to someone with 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 (1e820764c1ba5f94)', Time: '2020-11-30T13:55:35', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '9c11f119-1700-4c76-8bcb-1a6dec1d8866'	System	30 Nov 2020 18:55:41
User entered 'No (N)'	System	30 Nov 2020 18:55:41

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-11-30T13:55:38', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '9c11f119-1700-4c76-8bcb-1a6dec1d8866'	System	30 Nov 2020 18:55:41
User entered '30 Nov 2020 13:55:38'	System	30 Nov 2020 18:55:41



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[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 (1e820764c1ba5f94)', Time: '2020-12-03T06:18:52', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '4d0eadb8-9844-4780-b1a5-a8fd015d4fd8'	System	03 Dec 2020 11:19:05
User entered 'No (N)'	System	03 Dec 2020 11:19:05

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Have you been exposed to someone with 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 (1e820764c1ba5f94)', Time: '2020-12-03T06:18:54', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '4d0eadb8-9844-4780-b1a5-a8fd015d4fd8'	System	03 Dec 2020 11:19:05
User entered 'No (N)'	System	03 Dec 2020 11:19:05

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-12-03T06:19:02', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '4d0eadb8-9844-4780-b1a5-a8fd015d4fd8'	System	03 Dec 2020 11:19:05
User entered '03 Dec 2020 06:19:02'	System	03 Dec 2020 11:19:05

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[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 (1e820764c1ba5f94)', Time: '2020-12-10T00:46:47', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'e2ea2550-e967-4557-b6e5-a5615a21467b'	System	10 Dec 2020 05:47:07
User entered 'No (N)'	System	10 Dec 2020 05:47:07

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Have you been exposed to someone with 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 (1e820764c1ba5f94)', Time: '2020-12-10T00:46:56', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'e2ea2550-e967-4557-b6e5-a5615a21467b'	System	10 Dec 2020 05:47:07
User entered 'No (N)'	System	10 Dec 2020 05:47:07

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-12-10T00:47:02', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'e2ea2550-e967-4557-b6e5-a5615a21467b' User entered '10 Dec 2020 00:47:02'	System	10 Dec 2020 05:47:07
	System	10 Dec 2020 05:47:07

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[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 (1e820764c1ba5f94)', Time: '2020-12-17T17:13:22', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'bca481a6-36aa-457c-bae0-62177cd9b5fc'	System	17 Dec 2020 22:13:34
User entered 'No (N)'	System	17 Dec 2020 22:13:34



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Have you been exposed to someone with 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 (1e820764c1ba5f94)', Time: '2020-12-17T17:13:28', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'bca481a6-36aa-457c-bae0-62177cd9b5fc'	System	17 Dec 2020 22:13:34
User entered 'No (N)'	System	17 Dec 2020 22:13:34

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-12-17T17:13:31', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'bca481a6-36aa-457c-bae0-62177cd9b5fc' User entered '17 Dec 2020 17:13:31'	System	17 Dec 2020 22:13:34
	System	17 Dec 2020 22:13:34

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[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 (1e820764c1ba5f94)', Time: '2020-12-24T07:34:48', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '9c250737-4f33-4bc0-b0c7-e74fd6f2cf5f' User entered 'No (N)'	System	24 Dec 2020 13:35:04

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Have you been exposed to someone with 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 (1e820764c1ba5f94)', Time: '2020-12-24T07:34:55', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '9c250737-4f33-4bc0-b0c7-e74fd6f2cf5f' User entered 'No (N)'	System	24 Dec 2020 13:35:04

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2020-12-24T07:35:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '9c250737-4f33-4bc0-b0c7-e74fd6f2cf5f' User entered '24 Dec 2020 07:35:00'	System	24 Dec 2020 13:35:04
	System	24 Dec 2020 13:35:04



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[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 (1e820764c1ba5f94)', Time: '2021-01-08T06:41:23', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'ab54c529-6da9-43d3-9ac6-eee0bf09137c'	System	08 Jan 2021 11:41:38
User entered 'No (N)'	System	08 Jan 2021 11:41:38

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Have you been exposed to someone with 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 (1e820764c1ba5f94)', Time: '2021-01-08T06:41:29', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'ab54c529-6da9-43d3-9ac6-eee0bf09137c'	System	08 Jan 2021 11:41:38
User entered 'No (N)'	System	08 Jan 2021 11:41:38



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2021-01-08T06:41:34', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'ab54c529-6da9-43d3-9ac6-eee0bf09137c'	System	08 Jan 2021 11:41:38
User entered '08 Jan 2021 06:41:34'	System	08 Jan 2021 11:41:38

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[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 (1e820764c1ba5f94)', Time: '2021-01-14T17:04:08', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '9069359b-4862-4bb8-bf37-940a856d7977'	System	14 Jan 2021 22:04:19
User entered 'No (N)'	System	14 Jan 2021 22:04:19

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Have you been exposed to someone with 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 (1e820764c1ba5f94)', Time: '2021-01-14T17:04:12', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '9069359b-4862-4bb8-bf37-940a856d7977'	System	14 Jan 2021 22:04:19
User entered 'No (N)'	System	14 Jan 2021 22:04:19

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2021-01-14T17:04:15', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '9069359b-4862-4bb8-bf37-940a856d7977'	System	14 Jan 2021 22:04:19
User entered '14 Jan 2021 17:04:15'	System	14 Jan 2021 22:04:19

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[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 (1e820764c1ba5f94)', Time: '2021-01-23T19:20:09', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'bfc410cb-00da-4838-a009-1ac9c8033d5b'	System	24 Jan 2021 00:20:22
User entered 'No (N)'	System	24 Jan 2021 00:20:22

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Have you been exposed to someone with 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 (1e820764c1ba5f94)', Time: '2021-01-23T19:20:12', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'bfc410cb-00da-4838-a009-1ac9c8033d5b'	System	24 Jan 2021 00:20:22
User entered 'No (N)'	System	24 Jan 2021 00:20:22

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2021-01-23T19:20:16', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'bfc410cb-00da-4838-a009-1ac9c8033d5b'	System	24 Jan 2021 00:20:22
User entered '23 Jan 2021 19:20:16'	System	24 Jan 2021 00:20:22

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[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 (1e820764c1ba5f94)', Time: '2021-01-29T13:00:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '3d51d96c-840b-4fae-bf8c-a7a40eaa8262'	System	29 Jan 2021 18:00:15
User entered 'No (N)'	System	29 Jan 2021 18:00:15

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Have you been exposed to someone with 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 (1e820764c1ba5f94)', Time: '2021-01-29T13:00:05', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '3d51d96c-840b-4fae-bf8c-a7a40eaa8262'	System	29 Jan 2021 18:00:15
User entered 'No (N)'	System	29 Jan 2021 18:00:15

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2021-01-29T13:00:09', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '3d51d96c-840b-4fae-bf8c-a7a40eaa8262'	System	29 Jan 2021 18:00:15
User entered '29 Jan 2021 13:00:09'	System	29 Jan 2021 18:00:15

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[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 (1e820764c1ba5f94)', Time: '2021-02-04T11:10:59', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'a6f50ba8-810e-4468-b581-6ccddfce5046'	System	04 Feb 2021 16:11:12
User entered 'No (N)'	System	04 Feb 2021 16:11:12

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Have you been exposed to someone with 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 (1e820764c1ba5f94)', Time: '2021-02-04T11:11:04', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'a6f50ba8-810e-4468-b581-6ccddfce5046'	System	04 Feb 2021 16:11:12
User entered 'No (N)'	System	04 Feb 2021 16:11:12



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2021-02-04T11:11:08', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'a6f50ba8-810e-4468-b581-6ccddfce5046'	System	04 Feb 2021 16:11:12
User entered '04 Feb 2021 11:11:08'	System	04 Feb 2021 16:11:12

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[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 (1e820764c1ba5f94)', Time: '2021-02-11T18:21:54', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '04484245-bbc0-4b9b-83ca-6581c4921522'	System	11 Feb 2021 23:23:46
User entered 'No (N)'	System	11 Feb 2021 23:23:46

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Have you been exposed to someone with 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 (1e820764c1ba5f94)', Time: '2021-02-11T18:21:57', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '04484245-bbc0-4b9b-83ca-6581c4921522'	System	11 Feb 2021 23:23:46
User entered 'No (N)'	System	11 Feb 2021 23:23:46

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2021-02-11T18:22:01', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '04484245-bbc0-4b9b-83ca-6581c4921522'	System	11 Feb 2021 23:23:46
User entered '11 Feb 2021 18:22:01'	System	11 Feb 2021 23:23:46

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[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 (1e820764c1ba5f94)', Time: '2021-02-18T12:06:02', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '2ab2fe28-4024-41a7-8fea-0e2ad9157da9'	System	18 Feb 2021 17:12:39
User entered 'No (N)'	System	18 Feb 2021 17:12:39

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Have you been exposed to someone with 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 (1e820764c1ba5f94)', Time: '2021-02-18T12:06:07', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '2ab2fe28-4024-41a7-8fea-0e2ad9157da9'	System	18 Feb 2021 17:12:39
User entered 'No (N)'	System	18 Feb 2021 17:12:39

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2021-02-18T12:06:11', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '2ab2fe28-4024-41a7-8fea-0e2ad9157da9' User entered '18 Feb 2021 12:06:11'	System	18 Feb 2021 17:12:39
	System	18 Feb 2021 17:12:39

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[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 (1e820764c1ba5f94)', Time: '2021-03-01T19:15:32-05:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '0b07b46b-efc1-43da-af66-ca9b6106d535'	System	02 Mar 2021 00:18:26
User entered 'No (N)'	System	02 Mar 2021 00:18:26

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Have you been exposed to someone with 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 (1e820764c1ba5f94)', Time: '2021-03-01T19:15:37-05:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '0b07b46b-efc1-43da-af66-ca9b6106d535'	System	02 Mar 2021 00:18:26
User entered 'No (N)'	System	02 Mar 2021 00:18:26

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2021-03-01T19:15:42-05:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '0b07b46b-efc1-43da-af66-ca9b6106d535'	System	02 Mar 2021 00:18:26
User entered '01 Mar 2021 19:15:42'	System	02 Mar 2021 00:18:26

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[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 (1e820764c1ba5f94)', Time: '2021-03-04T11:07:44-05:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '6ca4b459-c8fc-410f-86d3-dced62fcf0b5'	System	04 Mar 2021 16:08:00
User entered 'No (N)'	System	04 Mar 2021 16:08:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Have you been exposed to someone with 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 (1e820764c1ba5f94)', Time: '2021-03-04T11:07:46-05:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '6ca4b459-c8fc-410f-86d3-dced62fcf0b5'	System	04 Mar 2021 16:08:00
User entered 'No (N)'	System	04 Mar 2021 16:08:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2021-03-04T11:07:49-05:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '6ca4b459-c8fc-410f-86d3-dced62fcf0b5'	System	04 Mar 2021 16:08:00
User entered '04 Mar 2021 11:07:49'	System	04 Mar 2021 16:08:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[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 (1e820764c1ba5f94)', Time: '2021-03-11T07:00:53-05:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'ae251732-9935-4c5d-9801-4f66e2b025f3'	System	11 Mar 2021 12:01:09
User entered 'No (N)'	System	11 Mar 2021 12:01:09

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Have you been exposed to someone with 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 (1e820764c1ba5f94)', Time: '2021-03-11T07:00:57-05:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'ae251732-9935-4c5d-9801-4f66e2b025f3'	System	11 Mar 2021 12:01:09
User entered 'No (N)'	System	11 Mar 2021 12:01:09

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2021-03-11T07:01:01-05:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'ae251732-9935-4c5d-9801-4f66e2b025f3'	System	11 Mar 2021 12:01:09
User entered '11 Mar 2021 07:01:01'	System	11 Mar 2021 12:01:09

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[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 (1e820764c1ba5f94)', Time: '2021-03-20T21:30:49-04:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'c51586f2-80df-4b33-9a42-f5062d6a8e3e'	System	21 Mar 2021 01:30:59
User entered 'No (N)'	System	21 Mar 2021 01:30:59

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Have you been exposed to someone with 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 (1e820764c1ba5f94)', Time: '2021-03-20T21:30:51-04:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'c51586f2-80df-4b33-9a42-f5062d6a8e3e'	System	21 Mar 2021 01:30:59
User entered 'No (N)'	System	21 Mar 2021 01:30:59

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2021-03-20T21:30:55-04:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'c51586f2-80df-4b33-9a42-f5062d6a8e3e' User entered '20 Mar 2021 21:30:55'	System	21 Mar 2021 01:30:59

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[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 (1e820764c1ba5f94)', Time: '2021-03-25T06:50:23-04:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '9fb7e870-b991-4721-a78c-a3e74f7b631e'	System	25 Mar 2021 10:50:42
User entered 'No (N)'	System	25 Mar 2021 10:50:42

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Have you been exposed to someone with 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 (1e820764c1ba5f94)', Time: '2021-03-25T06:50:30-04:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '9fb7e870-b991-4721-a78c-a3e74f7b631e'	System	25 Mar 2021 10:50:42
User entered 'No (N)'	System	25 Mar 2021 10:50:42

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2021-03-25T06:50:38-04:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '9fb7e870-b991-4721-a78c-a3e74f7b631e' User entered '25 Mar 2021 06:50:38'	System	25 Mar 2021 10:50:42
	System	25 Mar 2021 10:50:42

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[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 (1e820764c1ba5f94)', Time: '2021-04-01T22:01:07-04:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'a89ae66d-c062-41ac-adbb-578e52d9b81e' User entered 'No (N)'	System	02 Apr 2021 02:03:25
	System	02 Apr 2021 02:03:25

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Have you been exposed to someone with 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 (1e820764c1ba5f94)', Time: '2021-04-01T22:01:10-04:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'a89ae66d-c062-41ac-adbb-578e52d9b81e'	System	02 Apr 2021 02:03:25
User entered 'No (N)'	System	02 Apr 2021 02:03:25



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2021-04-01T22:01:13-04:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'a89ae66d-c062-41ac-adbb-578e52d9b81e' User entered '01 Apr 2021 22:01:13'	System	02 Apr 2021 02:03:25

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[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 (1e820764c1ba5f94)', Time: '2021-04-08T14:35:53-04:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '7c2908b9-5bd5-41a1-ac59-e85d9baff507'	System	08 Apr 2021 18:36:13
User entered 'No (N)'	System	08 Apr 2021 18:36:13

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Have you been exposed to someone with 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 (1e820764c1ba5f94)', Time: '2021-04-08T14:36:01-04:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '7c2908b9-5bd5-41a1-ac59-e85d9baff507'	System	08 Apr 2021 18:36:13
User entered 'No (N)'	System	08 Apr 2021 18:36:13

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2021-04-08T14:36:05-04:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '7c2908b9-5bd5-41a1-ac59-e85d9baff507'	System	08 Apr 2021 18:36:13
User entered '08 Apr 2021 14:36:05'	System	08 Apr 2021 18:36:13

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[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 (1e820764c1ba5f94)', Time: '2021-04-18T19:44:35-04:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'cda4095a-1626-4434-945c-faae57752df7'	System	18 Apr 2021 23:44:47
User entered 'No (N)'	System	18 Apr 2021 23:44:47

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Have you been exposed to someone with 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 (1e820764c1ba5f94)', Time: '2021-04-18T19:44:37-04:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'cda4095a-1626-4434-945c-faae57752df7'	System	18 Apr 2021 23:44:47
User entered 'No (N)'	System	18 Apr 2021 23:44:47

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2021-04-18T19:44:40-04:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'cda4095a-1626-4434-945c-faae57752df7'	System	18 Apr 2021 23:44:47
User entered '18 Apr 2021 19:44:40'	System	18 Apr 2021 23:44:47

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[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 (1e820764c1ba5f94)', Time: '2021-04-22T07:02:16-04:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '1419d4e5-b274-4311-93bb-dd6f3b41a55f' User entered 'No (N)'	System	22 Apr 2021 11:02:43
	System	22 Apr 2021 11:02:43

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Have you been exposed to someone with 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 (1e820764c1ba5f94)', Time: '2021-04-22T07:02:32-04:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '1419d4e5-b274-4311-93bb-dd6f3b41a55f'	System	22 Apr 2021 11:02:43
User entered 'No (N)'	System	22 Apr 2021 11:02:43

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2021-04-22T07:02:36-04:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '1419d4e5-b274-4311-93bb-dd6f3b41a55f' User entered '22 Apr 2021 07:02:36'	System	22 Apr 2021 11:02:43
	System	22 Apr 2021 11:02:43

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[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 (1e820764c1ba5f94)', Time: '2021-04-29T22:56:22-04:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'c06c9ab0-39d1-4954-a8a7-8b1e191b23a7'	System	30 Apr 2021 02:57:25
User entered 'No (N)'	System	30 Apr 2021 02:57:25

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

Have you been exposed to someone with 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 (1e820764c1ba5f94)', Time: '2021-04-29T22:56:24-04:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'c06c9ab0-39d1-4954-a8a7-8b1e191b23a7'	System	30 Apr 2021 02:57:25
User entered 'No (N)'	System	30 Apr 2021 02:57:25



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2021-04-29T22:56:27-04:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: 'c06c9ab0-39d1-4954-a8a7-8b1e191b23a7'	System	30 Apr 2021 02:57:25
User entered '29 Apr 2021 22:56:27'	System	30 Apr 2021 02:57:25

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 02:33:00



**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 02:33:00

**US3902015**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:40:59**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:33:00
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 02:33:00

US3902015

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 12 Aug 2021 13:40:59**

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)	24 Apr 2021 06:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2021-03-01T19:15:51-05:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '2a2615b9-8c20-4eec-99a5-97b8d70dcf15'	System	02 Mar 2021 00:18:43
User entered 'No (N)'	System	02 Mar 2021 00:18:43

**US3902015**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:28:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1e820764c1ba5f94)', Time: '2021-03-01T19:15:55-05:00', User OID: 'PatientReportedOutcome (US3902015)', ODM File OID: '2a2615b9-8c20-4eec-99a5-97b8d70dcf15'	System	02 Mar 2021 00:18:43
User entered '01 Mar 2021 19:15:55'	System	02 Mar 2021 00:18:43

**US3902015**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'No (N)'	Taylor Atkinson (b) (4)	04 Jan 2021 20:09:31

US3902015

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Taylor Atkinson (b) (4)	04 Jan 2021 20:09:31

**US3902015**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Taylor Atkinson (b) (4)	04 Jan 2021 20:09:31



**US3902015**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Subject was in illness period during call window'	Taylor Atkinson (b) (4)	04 Jan 2021 20:09:31

**US3902015**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:40:59**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	04 Jan 2021 20:09:38

**US3902015**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:40:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:18:06
User entered 'I'	System	04 Jan 2021 20:09:38

**US3902015**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:18
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 15:16:32
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	04 Jan 2021 20:09:52

US3902015

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:18
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 15:16:32
User entered '4 Jan 2021'	Taylor Atkinson (b) (4)	04 Jan 2021 20:09:52

**US3902015**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:18
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 15:16:32
User entered 'Contact Made (CONTACT MADE)'	Taylor Atkinson (b) (4)	04 Jan 2021 20:09:52

**US3902015**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:18
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 15:16:32
User entered empty.	Taylor Atkinson (b) (4)	04 Jan 2021 20:09:52

US3902015

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:18
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 15:16:38
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	04 Jan 2021 20:09:59



**US3902015**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:40:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:18
User entered '1'	System	04 Jan 2021 20:09:59

**US3902015**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:18
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	02 Feb 2021 16:37:23

**US3902015**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:18
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '1 Feb 2021'	Bram Swarr (b) (4)	02 Feb 2021 16:37:23

**US3902015**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:18
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Contact Made (CONTACT MADE)'	Bram Swarr (b) (4)	02 Feb 2021 16:37:23

US3902015

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:18
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Bram Swarr (b) (4)	02 Feb 2021 16:37:23

US3902015

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:18
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	02 Feb 2021 16:37:30

**US3902015**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:40:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:18
User entered 'I'	System	02 Feb 2021 16:37:30

**US3902015**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:18
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Mar 2021 18:45:58



**US3902015**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:18
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '04 Mar 2021'	(b) (4), (b) (6)	26 Mar 2021 18:45:58

**US3902015**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:18
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	26 Mar 2021 18:45:58

US3902015

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:18
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 18:45:58

**US3902015**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:40:59**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:18
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Mar 2021 18:46:03

**US3902015**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:40:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:21:18
User entered 'I'	System	26 Mar 2021 18:46:03

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:40:59

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:01
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:20:03
User closed query 'Please reconcile and enter the severity page' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 05:02:00
Query 'Please reconcile and enter the severity page' answered with 'Severity page entered.' (Site from CRA).	Taylor Atkinson (b) (4)	04 Nov 2020 22:22:33
User opened query 'Please reconcile and enter the severity page' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 13:28:26
User entered '27 Oct 2020'	Taylor Atkinson (b) (4)	29 Oct 2020 17:07:41

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:40:59

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:01
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:20:03
User entered '14:00'	Taylor Atkinson (b) (4)	29 Oct 2020 17:07:41

**US3902015**

**Folder: Covid-19 Assessment 27 Oct 2020**

**Form: COVID-19 Contact**

**Generated On: 12 Aug 2021 13:40:59**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:01
User entered '27 Oct 2020 14:00'	System	29 Oct 2020 17:07:41



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:40:59

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:01
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:20:03
User entered 'Safety Call (Safety Call)'	Taylor Atkinson (b) (4)	29 Oct 2020 17:07:41

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:40:59

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:01
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:20:03
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	29 Oct 2020 17:07:41

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Day 1 (Day 1)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:07:14

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '26 Oct 2020'	Taylor Atkinson (b) (4)	03 Nov 2020 21:07:14

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '0'	Taylor Atkinson (b) (4)	03 Nov 2020 21:07:14

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered missing code ND - Not Done.	Taylor Atkinson (b) (4)	03 Nov 2020 21:07:14

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User entered '%'	System	03 Nov 2020 21:07:14

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered missing code ND - Not Done.	Taylor Atkinson (b) (4)	03 Nov 2020 21:07:14



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:07:14

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:07:14

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Not Done (Not Done)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:07:14

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Not Done (Not Done)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:07:14

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:07:14

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Not Done (Not Done)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:07:14

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:07:14

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Not Done (Not Done)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:07:14



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Not Done (Not Done)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:07:14

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Not Done (Not Done)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:07:14

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:07:14

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Not Done (Not Done)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:07:14

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Not Done (Not Done)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:07:14

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Not Done (Not Done)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:07:14

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Not Done (Not Done)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:07:14

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Not Done (Not Done)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:07:14



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Day 2 (Day 2)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:08:21

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '27 Oct 2020'	Taylor Atkinson (b) (4)	03 Nov 2020 21:08:21

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '0'	Taylor Atkinson (b) (4)	03 Nov 2020 21:08:21

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered missing code ND - Not Done.	Taylor Atkinson (b) (4)	03 Nov 2020 21:08:21

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User entered '%'	System	03 Nov 2020 21:08:21

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered missing code ND - Not Done.	Taylor Atkinson (b) (4)	03 Nov 2020 21:08:21

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:08:21

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:08:21



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Not Done (Not Done)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:08:21

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Not Done (Not Done)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:08:21

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:08:21

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Not Done (Not Done)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:08:21

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:08:21

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Not Done (Not Done)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:08:21

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Not Done (Not Done)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:08:21

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Not Done (Not Done)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:08:21



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:08:21

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Not Done (Not Done)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:08:21

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Not Done (Not Done)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:08:21

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Not Done (Not Done)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:08:21

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Not Done (Not Done)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:08:21

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Not Done (Not Done)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:08:21

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Day 3 (Day 3)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:11:20

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '28 Oct 2020'	Taylor Atkinson (b) (4)	03 Nov 2020 21:11:20



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '0'	Taylor Atkinson (b) (4)	03 Nov 2020 21:11:20

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered missing code ND - Not Done.	Taylor Atkinson (b) (4)	03 Nov 2020 21:11:20

**US3902015**

**Folder: Covid-19 Assessment 27 Oct 2020**

**Form: Symptom Log (3)**

**Generated On: 12 Aug 2021 13:40:59**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User entered '%'	System	03 Nov 2020 21:11:20

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '100.0' F	Taylor Atkinson (b) (4)	03 Nov 2020 21:11:20

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:11:20

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:11:20

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:11:20

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:11:20



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:11:20

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:11:20

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:11:20

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:11:20

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:11:20

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:11:20

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:11:20

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:11:20



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:11:20

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:11:20

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:11:20

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:11:20

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Day 4 (Day 4)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:13:07

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '29 Oct 2020'	Taylor Atkinson (b) (4)	03 Nov 2020 21:13:07

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '0'	Taylor Atkinson (b) (4)	03 Nov 2020 21:13:07

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '98'	Taylor Atkinson (b) (4)	03 Nov 2020 21:13:07



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User entered '%'	System	03 Nov 2020 21:13:07

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '102.4' F	Taylor Atkinson (b) (4)	03 Nov 2020 21:13:07

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Moderate (Moderate)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:13:07

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Moderate (Moderate)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:13:07

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:13:07

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Moderate (Moderate)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:13:07

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Moderate (Moderate)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:13:07

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Moderate (Moderate)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:13:07



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Moderate (Moderate)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:13:07

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:13:07

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:13:07

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:13:07

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:13:07

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:13:07

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:13:07

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:13:07



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:13:07

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:13:07

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'Please reconcile and add 31Oct20 - 03Nov20. As a reminder these are to be entered within 24 hrs of the call completion.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 05:02:18
Query 'Please reconcile and add 31Oct20 - 03Nov20. As a reminder these are to be entered within 24 hrs of the call completion.' answered with 'Added' (Site from CRA).	Taylor Atkinson (b) (4)	04 Nov 2020 21:38:12
User opened query 'Please reconcile and add 31Oct20 - 03Nov20. As a reminder these are to be entered within 24 hrs of the call completion.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 13:29:04
User entered 'Day 5 (Day 5)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:15:18

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '30 Oct 2020'	Taylor Atkinson (b) (4)	03 Nov 2020 21:15:18

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '0'	Taylor Atkinson (b) (4)	03 Nov 2020 21:15:18

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '98'	Taylor Atkinson (b) (4)	03 Nov 2020 21:15:18

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User entered '%'	System	03 Nov 2020 21:15:18

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '100.1' F	Taylor Atkinson (b) (4)	03 Nov 2020 21:15:18



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:15:18

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:15:18

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:15:18

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:15:18

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Moderate (Moderate)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:15:18

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Moderate (Moderate)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:15:18

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:15:18

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:15:18



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:15:18

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:15:18

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Moderate (Moderate)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:15:18

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:15:18

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:15:18

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:15:18

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:15:18

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	03 Nov 2020 21:15:18



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Day 6 (Day 6)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:31:59

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '31 Oct 2020'	Taylor Atkinson (b) (4)	04 Nov 2020 21:31:59

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '0'	Taylor Atkinson (b) (4)	04 Nov 2020 21:31:59

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '98'	Taylor Atkinson (b) (4)	04 Nov 2020 21:31:59

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User entered '%'	System	04 Nov 2020 21:31:59

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '99.7' F	Taylor Atkinson (b) (4)	04 Nov 2020 21:31:59

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:31:59

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:31:59



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:31:59

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:31:59

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:31:59

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Moderate (Moderate)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:31:59

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Moderate (Moderate)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:31:59

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:31:59

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:31:59

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:31:59



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:31:59

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:31:59

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:31:59

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:31:59

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:31:59

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:31:59

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Day 7 (Day 7)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:33:33

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '1 Nov 2020'	Taylor Atkinson (b) (4)	04 Nov 2020 21:33:33



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '0'	Taylor Atkinson (b) (4)	04 Nov 2020 21:33:33

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '98'	Taylor Atkinson (b) (4)	04 Nov 2020 21:33:33

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User entered '%'	System	04 Nov 2020 21:33:33

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '98.3' F	Taylor Atkinson (b) (4)	04 Nov 2020 21:33:33

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:33:33

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:33:33

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:33:33

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:33:33



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:33:33

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:33:33

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:33:33

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:33:33

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:33:33

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:33:33

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:33:33

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:33:33



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:33:33

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:33:33

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:33:33

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:33:33

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Day 8 (Day 8)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:34:52

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '2 Nov 2020'	Taylor Atkinson (b) (4)	04 Nov 2020 21:34:52

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '0'	Taylor Atkinson (b) (4)	04 Nov 2020 21:34:52

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '97'	Taylor Atkinson (b) (4)	04 Nov 2020 21:34:52



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User entered '%'	System	04 Nov 2020 21:34:52

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '98.4' F	Taylor Atkinson (b) (4)	04 Nov 2020 21:34:52

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:34:52

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:34:52

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:34:52

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:34:52

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:34:52

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:34:52



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:34:52

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:34:52

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:34:52

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:34:52

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:34:52

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:34:52

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:34:52

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:34:52



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:34:52

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:34:52

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Day 9 (Day 9)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:37:28

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '3 Nov 2020'	Taylor Atkinson (b) (4)	04 Nov 2020 21:37:28

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '0'	Taylor Atkinson (b) (4)	04 Nov 2020 21:37:28

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '96'	Taylor Atkinson (b) (4)	04 Nov 2020 21:37:28

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User entered '%'	System	04 Nov 2020 21:37:28

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '101.0' F	Taylor Atkinson (b) (4)	04 Nov 2020 21:37:28



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:37:28

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:37:28

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:37:28

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:37:28

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:37:28

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:37:28

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:37:28

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:37:28



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:37:28

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:37:28

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:37:28

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:37:28

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:37:28

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:37:28

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:37:28

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:37:28



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Day 10 (Day 10)'	Taylor Atkinson (b) (4)	05 Nov 2020 00:03:31

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '4 Nov 2020'	Taylor Atkinson (b) (4)	05 Nov 2020 00:03:31

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '0'	Taylor Atkinson (b) (4)	05 Nov 2020 00:03:31

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '95'	Taylor Atkinson (b) (4)	05 Nov 2020 00:03:31

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User entered '%'	System	05 Nov 2020 00:03:31

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '98.5' F	Taylor Atkinson (b) (4)	05 Nov 2020 00:03:31

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	05 Nov 2020 00:03:31

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	05 Nov 2020 00:03:31



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	05 Nov 2020 00:03:31

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	05 Nov 2020 00:03:31

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	05 Nov 2020 00:03:31

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	05 Nov 2020 00:03:31

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	05 Nov 2020 00:03:31

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	05 Nov 2020 00:03:31

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	05 Nov 2020 00:03:31

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	05 Nov 2020 00:03:31



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	05 Nov 2020 00:03:31

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	05 Nov 2020 00:03:31

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	05 Nov 2020 00:03:31

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	05 Nov 2020 00:03:31

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	05 Nov 2020 00:03:31

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	05 Nov 2020 00:03:31

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Day 11 (Day 11)'	Taylor Atkinson (b) (4)	06 Nov 2020 22:12:37

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '5 Nov 2020'	Taylor Atkinson (b) (4)	06 Nov 2020 22:12:37



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'I'	Taylor Atkinson (b) (4)	06 Nov 2020 22:12:37

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered empty.	Taylor Atkinson (b) (4)	06 Nov 2020 22:12:37

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User entered empty.	System	06 Nov 2020 22:12:37

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered empty.	Taylor Atkinson (b) (4)	06 Nov 2020 22:12:37

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered empty.	Taylor Atkinson (b) (4)	06 Nov 2020 22:12:37

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered empty.	Taylor Atkinson (b) (4)	06 Nov 2020 22:12:37

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered empty.	Taylor Atkinson (b) (4)	06 Nov 2020 22:12:37

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered empty.	Taylor Atkinson (b) (4)	06 Nov 2020 22:12:37



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered empty.	Taylor Atkinson (b) (4)	06 Nov 2020 22:12:37

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered empty.	Taylor Atkinson (b) (4)	06 Nov 2020 22:12:37

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered empty.	Taylor Atkinson (b) (4)	06 Nov 2020 22:12:37

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered empty.	Taylor Atkinson (b) (4)	06 Nov 2020 22:12:37

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered empty.	Taylor Atkinson (b) (4)	06 Nov 2020 22:12:37

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered empty.	Taylor Atkinson (b) (4)	06 Nov 2020 22:12:37

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered empty.	Taylor Atkinson (b) (4)	06 Nov 2020 22:12:37

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered empty.	Taylor Atkinson (b) (4)	06 Nov 2020 22:12:37



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered empty.	Taylor Atkinson (b) (4)	06 Nov 2020 22:12:37

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered empty.	Taylor Atkinson (b) (4)	06 Nov 2020 22:12:37

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered empty.	Taylor Atkinson (b) (4)	06 Nov 2020 22:12:37

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered empty.	Taylor Atkinson (b) (4)	06 Nov 2020 22:12:37

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Day 12 (Day 12)'	Taylor Atkinson (b) (4)	06 Nov 2020 22:13:47

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '6 Nov 2020'	Taylor Atkinson (b) (4)	06 Nov 2020 22:13:47

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '0'	Taylor Atkinson (b) (4)	06 Nov 2020 22:13:47

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:40:59

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'Per Figure 3/pg. 64 of A4 (30Sep2020), clinical signs indicative of severe symptomatic illness includes SpO2 <93%. Please confirm if subject had severe symptomatic disease. Per source mild SOB at time of contact. Please ensure source and EDC are updated accordingly.' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 17:48:16
Query 'Per Figure 3/pg. 64 of A4 (30Sep2020), clinical signs indicative of severe symptomatic illness includes SpO2 <93%. Please confirm if subject had severe symptomatic disease. Per source mild SOB at time of contact. Please ensure source and EDC are updated accordingly.' answered with 'Subject's pulse ox was recorded as 92% for one day, and then it went back to normal range. This was not a prolonged symptom, and subject did not seek medical attention after their initial diagnosis. ' (Site from CRA).	Taylor Atkinson (b) (4)	23 Feb 2021 14:48:57
User opened query 'Per Figure 3/pg. 64 of A4 (30Sep2020), clinical signs indicative of severe symptomatic illness includes SpO2 <93%. Please confirm if subject had severe symptomatic disease. Per source mild SOB at time of contact. Please ensure source and EDC are updated accordingly.' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 15:25:27
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '92'	Taylor Atkinson (b) (4)	06 Nov 2020 22:13:47



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User entered '%'	System	06 Nov 2020 22:13:47

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '99.1' F	Taylor Atkinson (b) (4)	06 Nov 2020 22:13:47

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	06 Nov 2020 22:13:47

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	06 Nov 2020 22:13:47

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Moderate (Moderate)'	Taylor Atkinson (b) (4)	06 Nov 2020 22:13:47

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	06 Nov 2020 22:13:47

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	06 Nov 2020 22:13:47

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Moderate (Moderate)'	Taylor Atkinson (b) (4)	06 Nov 2020 22:13:47



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Moderate (Moderate)'	Taylor Atkinson (b) (4)	06 Nov 2020 22:13:47

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	06 Nov 2020 22:13:47

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	06 Nov 2020 22:13:47

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	06 Nov 2020 22:13:47

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	06 Nov 2020 22:13:47

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	06 Nov 2020 22:13:47

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	06 Nov 2020 22:13:47

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	06 Nov 2020 22:13:47



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	06 Nov 2020 22:13:47

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	06 Nov 2020 22:13:47

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Day 13 (Day 13)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:48:43

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '7 Nov 2020'	Taylor Atkinson (b) (4)	09 Nov 2020 12:48:43

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '0'	Taylor Atkinson (b) (4)	09 Nov 2020 12:48:43

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '97'	Taylor Atkinson (b) (4)	09 Nov 2020 12:48:43

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User entered '%'	System	09 Nov 2020 12:48:43

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '97.9' F	Taylor Atkinson (b) (4)	09 Nov 2020 12:48:43



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:48:43

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:48:43

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:48:43

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:48:43

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:48:43

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:48:43

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:48:43

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:48:43



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:48:43

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:48:43

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:48:43

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:48:43

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:48:43

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:48:43

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:48:43

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:48:43



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Day 14 (Day 14)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:49:41

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '8 Nov 2020'	Taylor Atkinson (b) (4)	09 Nov 2020 12:49:41

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '0'	Taylor Atkinson (b) (4)	09 Nov 2020 12:49:41

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '98'	Taylor Atkinson (b) (4)	09 Nov 2020 12:49:41

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User entered '%'	System	09 Nov 2020 12:49:41

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '98.1' F	Taylor Atkinson (b) (4)	09 Nov 2020 12:49:41

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:49:41

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:49:41



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:49:41

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:49:41

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:49:41

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:49:41

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:49:41

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:49:41

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:49:41

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:49:41



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:49:41

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:49:41

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:49:41

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:49:41

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:49:41

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	09 Nov 2020 12:49:41

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Day 15 (Day 15)'	Taylor Atkinson (b) (4)	10 Nov 2020 19:31:32

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '9 Nov 2020'	Taylor Atkinson (b) (4)	10 Nov 2020 19:31:32



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '0'	Taylor Atkinson (b) (4)	10 Nov 2020 19:31:32

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered missing code ND - Not Done.	Taylor Atkinson (b) (4)	10 Nov 2020 19:31:32

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User entered '%'	System	10 Nov 2020 19:31:32

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered missing code ND - Not Done.	Taylor Atkinson (b) (4)	10 Nov 2020 19:31:32

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	10 Nov 2020 19:31:32

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	10 Nov 2020 19:31:32

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	10 Nov 2020 19:31:32

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	10 Nov 2020 19:31:32



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	10 Nov 2020 19:31:32

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)'	Taylor Atkinson (b) (4)	10 Nov 2020 19:31:32

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'Mild (Mild)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	10 Nov 2020 19:33:42
User entered 'None (None)'	Taylor Atkinson (b) (4)	10 Nov 2020 19:31:32

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	10 Nov 2020 19:31:32

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	10 Nov 2020 19:31:32

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	10 Nov 2020 19:31:32

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	10 Nov 2020 19:31:32

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	10 Nov 2020 19:31:32



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	10 Nov 2020 19:31:32

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	10 Nov 2020 19:31:32

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	10 Nov 2020 19:31:32

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	10 Nov 2020 19:31:32

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Day 16 (Day 16)'	Taylor Atkinson (b) (4)	10 Nov 2020 20:02:57

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:46:23
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 15:56:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '10 Nov 2020'	Taylor Atkinson (b) (4)	10 Nov 2020 20:02:57

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:46:23
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 15:56:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '0'	Taylor Atkinson (b) (4)	10 Nov 2020 20:02:57

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:46:23
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 15:56:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '98'	Taylor Atkinson (b) (4)	10 Nov 2020 20:02:57



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User entered '%'	System	10 Nov 2020 20:02:57

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:46:23
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 15:56:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered '97.1' F	Taylor Atkinson (b) (4)	10 Nov 2020 20:02:57

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:46:23
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 15:56:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	10 Nov 2020 20:02:57

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:46:23
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 15:56:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	10 Nov 2020 20:02:57

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:46:23
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 15:56:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	10 Nov 2020 20:02:57

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:46:23
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 15:56:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	10 Nov 2020 20:02:57

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:46:23
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 15:56:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	10 Nov 2020 20:02:57

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:46:23
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 15:56:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	10 Nov 2020 20:02:57



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:46:23
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 15:56:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	10 Nov 2020 20:02:57

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:46:23
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 15:56:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	10 Nov 2020 20:02:57

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:46:23
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 15:56:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	10 Nov 2020 20:02:57

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:46:23
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 15:56:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	10 Nov 2020 20:02:57

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:46:23
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 15:56:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	10 Nov 2020 20:02:57

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:46:23
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 15:56:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	10 Nov 2020 20:02:57

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:46:23
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 15:56:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	10 Nov 2020 20:02:57

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:46:23
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 15:56:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	10 Nov 2020 20:02:57



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:46:23
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 15:56:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	10 Nov 2020 20:02:57

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:09
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:46:23
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 15:56:58
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:02
User entered 'None (None)'	Taylor Atkinson (b) (4)	10 Nov 2020 20:02:57

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:40:59

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:16
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:12
User entered '28 Oct 2020'	Taylor Atkinson (b) (4)	29 Oct 2020 17:08:04

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:40:59

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:16
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:12
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	29 Oct 2020 17:08:04

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:40:59

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:16
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:12
Query 'Per CDM: Re-Query: Response noted. However, in Covid diagnostic test form it was reported that test was conducted on 28-OCT-20. But in AE page, AE start date for the event 'SYMPTOMATIC COVID-19' was reported as 26-OCT-20. Please review and update as appropriate. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:15:29
User opened query 'Per CDM: Re-Query: Response noted. However, in Covid diagnostic test form it was reported that test was conducted on 28-OCT-20. But in AE page, AE start date for the event 'SYMPTOMATIC COVID-19' was reported as 26-OCT-20. Please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 12:28:28
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	06 Nov 2020 12:27:44
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 'Confirmed test result was positive. AE has already been entered' (Site from System).	Taylor Atkinson (b) (4)	03 Nov 2020 21:05:24
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 15:44:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 15:44:20
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	03 Nov 2020 15:44:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	03 Nov 2020 15:44:20

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:40:59

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 17:08:04
User entered empty.	Taylor Atkinson (b) (4) (b) (4)	29 Oct 2020 17:08:04

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:40:59

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:16
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:12
User entered '28 Oct 2020'	Taylor Atkinson (b) (4)	29 Oct 2020 17:08:04

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:40:59

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:16
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:12
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Taylor Atkinson (b) (4)	29 Oct 2020 17:08:04



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:40:59

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:16
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:12
User entered empty.	Taylor Atkinson (b) (4)	29 Oct 2020 17:08:04

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:40:59

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:16
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:12
User entered 'No (N)'	Taylor Atkinson (b) (4)	29 Oct 2020 17:08:04

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:40:59

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:16
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:12
User entered empty.	Taylor Atkinson (b) (4)	29 Oct 2020 17:08:04

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:40:59

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:16
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:28:12
User entered empty.	Taylor Atkinson (b) (4)	29 Oct 2020 17:08:04

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:40:59

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:16
User entered 'I'	System	03 Nov 2020 15:44:20

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:40:59

Did the subject have Respiratory Rates  $\geq$  30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:18
User entered 'No (N)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:39:46

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:40:59

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:18
User entered empty.	Taylor Atkinson (b) (4)	04 Nov 2020 21:39:46

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:40:59

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:18
User entered empty.	Taylor Atkinson (b) (4)	04 Nov 2020 21:39:46



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:40:59

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:18
User entered empty.	Taylor Atkinson (b) (4)	04 Nov 2020 21:39:46

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:40:59

Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:18
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 21:40:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Nov 2020 21:40:09
User entered 'No (N)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	04 Nov 2020 21:40:09
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 21:39:46
User entered empty.	Taylor Atkinson (b) (4)	04 Nov 2020 21:39:46

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:40:59

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:18
User entered empty.	Taylor Atkinson (b) (4)	04 Nov 2020 21:39:46

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:40:59

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:18
User entered empty.	Taylor Atkinson (b) (4)	04 Nov 2020 21:39:46

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:40:59

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:18
User entered empty.	Taylor Atkinson (b) (4)	04 Nov 2020 21:39:46

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:40:59

Did the subject have Oxygen Saturation of SpO2  $\leq$  93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	06 Nov 2020 22:10:46
User entered 'No (N)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:39:46

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:40:59

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:18
User entered '6 Nov 2020' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	06 Nov 2020 22:10:46
User entered empty.	Taylor Atkinson (b) (4)	04 Nov 2020 21:39:46

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:40:59

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:18
User entered '6 Nov 2020' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	10 Nov 2020 19:28:51
User entered empty.	Taylor Atkinson (b) (4)	04 Nov 2020 21:39:46



US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:40:59

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:18
User entered '92' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	06 Nov 2020 22:10:46
User entered empty.	Taylor Atkinson (b) (4)	04 Nov 2020 21:39:46

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:40:59

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:18
User entered 'No (N)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:39:46

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:40:59

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:18
User entered empty.	Taylor Atkinson (b) (4)	04 Nov 2020 21:39:46

US3902015

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:18
User entered empty.	Taylor Atkinson (b) (4)	04 Nov 2020 21:39:46

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:40:59

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:18
User entered empty.	Taylor Atkinson (b) (4)	04 Nov 2020 21:39:46

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:40:59

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is recorded for 'If Yes to either Did subject require any of the following'. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 17:54:58
Query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is recorded for 'If Yes to either Did subject require any of the following'. Please review and update accordingly. ' answered with 'updated' (Site from DM).	Bram Swarr (b) (4)	19 Feb 2021 20:59:57
User opened query 'Per CDM: It appears that both 'Did the subject have Respiratory failure?' and 'Did the subject have Acute Respiratory Distress Syndrome (ARDS)?' is 'No', yet data is recorded for 'If Yes to either Did subject require any of the following'. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	14 Feb 2021 22:07:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:18
User entered 'No (N)'	Taylor Atkinson (b) (4) (b) (4)	04 Nov 2020 21:39:46

US3902015

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:18
User entered empty.	Taylor Atkinson (b) (4)	04 Nov 2020 21:39:46

US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:40:59

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:18
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US3902015

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User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:18
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US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:40:59

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 23:26:30
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Un-verified.	Bram Swarr (b) (4)	19 Feb 2021 20:59:43
User entered empty; reason for change Data Entry Error	Bram Swarr (b) (4)	19 Feb 2021 20:59:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:18
User entered 'No (N)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:39:46

US3902015

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
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US3902015

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:18
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US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:40:59

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 23:26:32
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Un-verified.	Bram Swarr (b) (4)	19 Feb 2021 20:59:43
User entered empty; reason for change Data Entry Error	Bram Swarr (b) (4)	19 Feb 2021 20:59:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:18
User entered 'No (N)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:39:46

US3902015

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US3902015

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:18
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US3902015

Folder: Covid-19 Assessment 27 Oct 2020

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Generated On: 12 Aug 2021 13:40:59

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 23:26:37
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Un-verified.	Bram Swarr (b) (4)	19 Feb 2021 20:59:43
User entered empty; reason for change Data Entry Error	Bram Swarr (b) (4)	19 Feb 2021 20:59:43
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:29:18
User entered 'No (N)'	Taylor Atkinson (b) (4)	04 Nov 2020 21:39:46



US3902015

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US3902015

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US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:40:59

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 23:26:47
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Un-verified.	Bram Swarr (b) (4)	19 Feb 2021 20:59:43
User entered empty; reason for change Data Entry Error	Bram Swarr (b) (4)	19 Feb 2021 20:59:43
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US3902015

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US3902015

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Generated On: 12 Aug 2021 13:40:59

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 23:26:47
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Un-verified.	Bram Swarr (b) (4)	19 Feb 2021 20:59:43
User entered empty; reason for change Data Entry Error	Bram Swarr (b) (4)	19 Feb 2021 20:59:43
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US3902015

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US3902015

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US3902015

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[Evidence of Shock Requires  
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 23:26:47
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US3902015

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US3902015

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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 23:26:47
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Un-verified.	Bram Swarr (b) (4)	19 Feb 2021 20:59:43
User entered empty; reason for change Data Entry Error	Bram Swarr (b) (4)	19 Feb 2021 20:59:43
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US3902015

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US3902015

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Generated On: 12 Aug 2021 13:40:59

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 23:26:47
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Un-verified.	Bram Swarr (b) (4)	19 Feb 2021 20:59:43
User entered empty; reason for change Data Entry Error	Bram Swarr (b) (4)	19 Feb 2021 20:59:43
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US3902015

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US3902015

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[Neurologic Dysfunction?](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 23:26:47
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Un-verified.	Bram Swarr (b) (4)	19 Feb 2021 20:59:43
User entered empty; reason for change Data Entry Error	Bram Swarr (b) (4)	19 Feb 2021 20:59:43
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US3902015

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US3902015

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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 23:26:47
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US3902015

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US3902015

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[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
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US3902015

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Generated On: 12 Aug 2021 13:40:59

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:24
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 23:26:47
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Feb 2021 21:00:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Feb 2021 21:00:29
User entered 'No (N)' reason for change: Data Entry Error	Bram Swarr (b) (4)	19 Feb 2021 21:00:29
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Feb 2021 20:59:43
DataPoint Un-verified.	Bram Swarr (b) (4)	19 Feb 2021 20:59:43
User entered empty; reason for change Data Entry Error	Bram Swarr (b) (4)	19 Feb 2021 20:59:43
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US3902015

Folder: Covid-19 Assessment 27 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:40:59

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:32
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	29 Oct 2020 17:08:13

**US3902015**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:48:23
User accepted default value 'Day 3 (Day 3)'	Taylor Atkinson (b) (4)	04 Nov 2020 14:37:43

US3902015

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:40:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:48:23
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'please confirm if saliva samples were shipped provide requisition number below. D3-D21 is filed, but no dates listed for D3, D5, D7,D9,and D21. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	21 Dec 2020 18:52:08
Query 'please confirm if saliva samples were shipped provide requisition number below. D3-D21 is filed, but no dates listed for D3, D5, D7,D9,and D21. Please reconcile.' answered with 'PD has been created for D21. D3, D5, D7, and D9 have been shipped to viracor' (Site from CRA).	Taylor Atkinson (b) (4)	15 Dec 2020 23:10:53
User opened query 'please confirm if saliva samples were shipped provide requisition number below. D3-D21 is filed, but no dates listed for D3, D5, D7,D9,and D21. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	07 Dec 2020 17:15:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:42:08
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	04 Nov 2020 14:37:43

US3902015

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:40:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:48:23
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Response noted, please confirm if sample has been shipped. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 10:34:21
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Response noted, please confirm if sample has been shipped. Thank you.' answered with ' D3, D5, D7, and D9 have been shipped to viracor' (Site from DM).	Taylor Atkinson (b) (4)	15 Dec 2020 23:11:01
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Response noted, please confirm if sample has been shipped. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 11:01:43
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020, 01NOV2020, 03NOV2020, 05NOV2020 and 10NOV2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 11:01:43
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020, 01NOV2020, 03NOV2020, 05NOV2020 and 10NOV2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Subject misplaced requisition' (Site from DM).	Taylor Atkinson (b) (4)	06 Dec 2020 21:08:26

US3902015

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:40:59

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020, 01NOV2020, 03NOV2020, 05NOV2020 and 10NOV2020 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 10:46:42
	(b) (4), (b) (6)	10 Nov 2020 22:42:08
User entered '30 Oct 2020'	Taylor Atkinson (b) (4)	04 Nov 2020 14:37:43
	(b) (4)	

**US3902015**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:48:23
User accepted default value 'Day 5 (Day 5)'	Taylor Atkinson (b) (4)	04 Nov 2020 14:37:43

**US3902015**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:48:23
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:42:08
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	04 Nov 2020 14:37:43

US3902015

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:40:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:48:23
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:42:08
User entered '1 Nov 2020'	Taylor Atkinson (b) (4)	04 Nov 2020 14:37:43



**US3902015**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 12 Aug 2021 13:40:59**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:48:23
User accepted default value 'Day 7 (Day 7)'	Taylor Atkinson (b) (4)	04 Nov 2020 14:37:43

**US3902015**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 12 Aug 2021 13:40:59**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:48:23
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:42:08
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	04 Nov 2020 14:37:43

**US3902015**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 12 Aug 2021 13:40:59**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:48:23
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:42:08
User entered '3 Nov 2020'	Taylor Atkinson (b) (4)	04 Nov 2020 14:37:43

**US3902015**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 12 Aug 2021 13:40:59**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:48:23
User accepted default value 'Day 9 (Day 9)'	Taylor Atkinson (b) (4)	04 Nov 2020 14:37:43

US3902015

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:40:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:48:23
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:17:25
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 22:43:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:42:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	10 Nov 2020 22:23:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	06 Nov 2020 12:34:39
Query 'Data is required. Please complete.' answered with 'Saliva collection still ongoing' (Site from System).	Taylor Atkinson (b) (4)	04 Nov 2020 22:23:00
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 14:37:43
User entered empty.	Taylor Atkinson (b) (4)	04 Nov 2020 14:37:43

US3902015

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:40:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:48:23
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:17:25
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 22:43:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:42:08
User entered '05 Nov 2020' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	10 Nov 2020 22:23:59
User entered empty.	Taylor Atkinson (b) (4)	04 Nov 2020 14:37:43

**US3902015**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 12 Aug 2021 13:40:59**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:48:23
User accepted default value 'Day 14 (Day 14)'	Taylor Atkinson (b) (4)	04 Nov 2020 14:37:43

US3902015

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:40:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:48:23
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:17:25
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 22:43:05
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:42:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	10 Nov 2020 22:23:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	06 Nov 2020 12:34:43
Query 'Data is required. Please complete.' answered with 'Saliva collection still ongoing' (Site from System).	Taylor Atkinson (b) (4)	04 Nov 2020 22:23:12
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 14:37:43
User entered empty.	Taylor Atkinson (b) (4)	04 Nov 2020 14:37:43



US3902015

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:40:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:48:23
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:17:25
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 22:43:05
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:42:08
User entered '10 Nov 2020' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	10 Nov 2020 22:23:59
User entered empty.	Taylor Atkinson (b) (4)	04 Nov 2020 14:37:43

**US3902015**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 12 Aug 2021 13:40:59**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:48:23
User accepted default value 'Day 21 (Day 21)'	Taylor Atkinson (b) (4)	04 Nov 2020 14:37:43
	(b) (4)	

US3902015

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:40:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:48:23
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:52:40
User entered 'No (N)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	06 Dec 2020 21:05:34
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 23:21:24
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:42:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	06 Nov 2020 12:34:47
Query 'Data is required. Please complete.' answered with 'Saliva collection still ongoing' (Site from System).	Taylor Atkinson (b) (4)	04 Nov 2020 22:23:22
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 14:37:43
User entered empty.	Taylor Atkinson (b) (4)	04 Nov 2020 14:37:43

**US3902015**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 12 Aug 2021 13:40:59**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:48:23
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:52:42
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 23:21:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:42:08
User entered empty.	Taylor Atkinson (b) (4)	04 Nov 2020 14:37:43

**US3902015**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 12 Aug 2021 13:40:59**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:48:23
User accepted default value 'Day 28 (Day 28)'	Taylor Atkinson (b) (4)	04 Nov 2020 14:37:43
	(b) (4)	

US3902015

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:40:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:48:23
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:52:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	06 Dec 2020 21:05:34
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 23:21:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:42:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	06 Nov 2020 12:34:53
Query 'Data is required. Please complete.' answered with 'Saliva collection still ongoing' (Site from System).	Taylor Atkinson (b) (4)	04 Nov 2020 22:23:28
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Nov 2020 14:37:43
User entered empty.	Taylor Atkinson (b) (4)	04 Nov 2020 14:37:43

US3902015

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:40:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:48:23
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:52:57
User entered '30 Nov 2020' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	06 Dec 2020 21:05:34
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 23:21:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:42:08
User entered empty.	Taylor Atkinson (b) (4)	04 Nov 2020 14:37:43

US3902015

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:40:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:47
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'Please reconcile saliva log for all samples collected to date' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 14:41:17
Query 'Please reconcile saliva log for all samples collected to date' answered with 'Saliva log up to date for all samples collected thus far' (Site from CRA).	Taylor Atkinson (b) (4)	04 Nov 2020 22:24:27
User opened query 'Please reconcile saliva log for all samples collected to date' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 13:29:33
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:13:33
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	29 Oct 2020 17:12:32



US3902015

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:40:59

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:47
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06NOV2020 and 07NOV2020 is reported under Illness visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 10:55:04
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06NOV2020 and 07NOV2020 is reported under Illness visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'Subject misunderstood the saliva collection directions. Subject took additional samples. Site has corresponded with viracor about this issue' (Site from DM).	Taylor Atkinson (b) (4)	23 Feb 2021 14:49:47
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06NOV2020 and 07NOV2020 is reported under Illness visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 07:51:31
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12DEC2020 and 14DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 06:09:46

US3902015

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:40:59

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12DEC2020 and 14DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'per progress notes, no illness visits occurred during that time. subject dropped off saliva samples for day 3,5,7, and 9 leaving us two extra samples which were shipped, but these were left with us 01dec2020.' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 12DEC2020 and 14DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	Bram Swarr (b) (4)	08 Jan 2021 21:13:54
DataPoint Verified.	(b) (4), (b) (6)	24 Dec 2020 09:20:08
User entered '28 Oct 2020'	Taylor Atkinson (b) (4)	30 Oct 2020 19:13:33
	(b) (4)	29 Oct 2020 17:12:32

US3902015

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:40:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:47
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:13:33
User entered 'Clinic (Clinic)'	Taylor Atkinson (b) (4)	29 Oct 2020 17:12:32

**US3902015**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:40:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:47
User entered 'SICKD1'	System	29 Oct 2020 17:12:32

US3902015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:58
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:13:50
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	29 Oct 2020 17:40:39

US3902015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:58
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:13:50
User entered '28 Oct 2020'	Taylor Atkinson (b) (4)	29 Oct 2020 17:40:39

US3902015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:58
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:13:50
User entered '15:35'	Taylor Atkinson (b) (4)	29 Oct 2020 17:40:39

**US3902015**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:58
User entered '28 Oct 2020 15:35'	System	29 Oct 2020 17:40:39



US3902015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:58
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:13:50
User entered '66.0' in reason for change: Data Entry Error	Taylor Atkinson (b) (4)	29 Oct 2020 17:40:58
User entered '66' in	Taylor Atkinson (b) (4)	29 Oct 2020 17:40:39
DataPoint set to visible.	System	29 Oct 2020 17:12:32

US3902015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:58
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:13:50
User entered '268.0' lb reason for change: Data Entry Error	Taylor Atkinson (b) (4)	29 Oct 2020 17:40:58
User entered '268' lb	Taylor Atkinson (b) (4)	29 Oct 2020 17:40:39
DataPoint set to visible.	System	29 Oct 2020 17:12:32

US3902015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:58
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:13:50
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Oct 2020 17:40:48
User entered '100.0' F reason for change: Data Entry Error	Taylor Atkinson (b) (4)	29 Oct 2020 17:40:48
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Oct 2020 17:40:39
User entered '100' (non-conformant).	Taylor Atkinson (b) (4)	29 Oct 2020 17:40:39

US3902015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:58
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:13:50
User entered 'Oral (Oral)'	Taylor Atkinson (b) (4)	29 Oct 2020 17:40:39

US3902015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:58
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:13:50
User entered empty.	Taylor Atkinson (b) (4)	29 Oct 2020 17:40:39

US3902015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:58
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:13:50
User entered '95'	Taylor Atkinson (b) (4)	29 Oct 2020 17:40:39

**US3902015**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:58
User entered 'bpm'	System	29 Oct 2020 17:40:39

US3902015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:58
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:13:50
User entered '16'	Taylor Atkinson (b) (4)	29 Oct 2020 17:40:39



US3902015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:58
User entered 'breaths/min'	System	29 Oct 2020 17:40:39

US3902015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:58
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:13:50
User entered '122'	Taylor Atkinson (b) (4)	29 Oct 2020 17:40:39

**US3902015**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:58
User entered 'mmHg'	System	29 Oct 2020 17:40:39

US3902015

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:58
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:13:50
User entered '70'	Taylor Atkinson (b) (4)	29 Oct 2020 17:40:39

**US3902015**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:58
User entered 'mmHg'	System	29 Oct 2020 17:40:39

**US3902015**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:58

**US3902015**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:46:58

US3902015

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:40:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:47:05
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:14:23
User entered 'No (N)'	Taylor Atkinson (b) (4)	29 Oct 2020 17:12:38



US3902015

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:40:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:47:05
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:14:23
User entered empty.	Taylor Atkinson (b) (4)	29 Oct 2020 17:12:38

US3902015

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:40:59

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:47:12
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:14:42
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	29 Oct 2020 17:12:49

**US3902015**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 12 Aug 2021 13:40:59**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:47:12
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 19:14:42
User entered '28 Oct 2020'	Taylor Atkinson (b) (4)	29 Oct 2020 17:12:49

US3902015

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:40:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:47:40
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:49:23
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	06 Dec 2020 21:05:56

US3902015

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:40:59

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:47:40
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06NOV2020 for Day 14, 07NOV2020 for Day 21 is reported under Illness visit (2) in preclarus report, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, if no sample collected on this day then please consider to update the Preclarus data via DCF to which subject it belongs to and also confirm the correct Subject ID and Visit in query response, thank you.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:42:50
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06NOV2020 for Day 14, 07NOV2020 for Day 21 is reported under Illness visit (2) in preclarus report, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, if no sample collected on this day then please consider to update the Preclarus data via DCF to which subject it belongs to and also confirm the correct Subject ID and Visit in query response, thank you.' answered with 'Subject inadvertently collected too many saliva samples in the beginning of the illness period, so site dispensed a second saliva kit. ' (Site from DM).	Taylor Atkinson (b) (4)	07 Apr 2021 13:07:40
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06NOV2020 for Day 14, 07NOV2020 for Day 21 is reported under Illness visit (2) in preclarus report, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, if no sample collected on this day then please consider to update the Preclarus data via DCF to which subject it belongs to and also confirm the correct Subject ID and Visit in query response, thank you.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 07:25:52

US3902015

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:40:59

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
	(b) (4), (b) (6)	21 Jan 2021 06:10:06
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06NOV2020 and 07NOV2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).		
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06NOV2020 and 07NOV2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'sample was collected in error by the subject; they left us samples for days 3,5,7, and 9 leaving us with two extra samples.' (Site from DM).	Bram Swarr (b) (4)	08 Jan 2021 21:15:50
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06NOV2020 and 07NOV2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 09:18:32
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:49:23
User entered '30 Nov 2020'	Taylor Atkinson (b) (4)	06 Dec 2020 21:05:56
	(b) (4)	

US3902015

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:40:59

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:47:40
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:49:23
User entered 'Clinic (Clinic)'	Taylor Atkinson (b) (4)	06 Dec 2020 21:05:56

**US3902015**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:40:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:47:40
User entered 'SICKD28'	System	06 Dec 2020 21:05:56



US3902015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:47:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:51:05
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	06 Dec 2020 21:06:51

US3902015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:47:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:51:05
User entered '30 Nov 2020'	Taylor Atkinson (b) (4)	06 Dec 2020 21:06:51

US3902015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:47:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:51:05
User entered '13:10'	Taylor Atkinson (b) (4)	06 Dec 2020 21:06:51

**US3902015**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:47:48
User entered '30 Nov 2020 13:10'	System	06 Dec 2020 21:06:51

US3902015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:47:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:51:05
User entered '66' in	Taylor Atkinson (b) (4)	06 Dec 2020 21:06:51
DataPoint set to visible.	(b) (4) System	06 Dec 2020 21:05:56

US3902015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:47:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:51:05
User entered '265' lb	Taylor Atkinson (b) (4)	06 Dec 2020 21:06:51
DataPoint set to visible.	(b) (4) System	06 Dec 2020 21:05:56

US3902015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:47:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:51:05
User entered '97.9' F	Taylor Atkinson (b) (4)	06 Dec 2020 21:06:51

US3902015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:47:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:51:05
User entered 'Oral (Oral)'	Taylor Atkinson (b) (4)	06 Dec 2020 21:06:51



US3902015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:47:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:51:05
User entered empty.	Taylor Atkinson (b) (4)	06 Dec 2020 21:06:51

US3902015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:47:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:51:05
User entered '81'	Taylor Atkinson (b) (4)	06 Dec 2020 21:06:51

**US3902015**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:47:48
User entered 'bpm'	System	06 Dec 2020 21:06:51

US3902015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:47:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:51:05
User entered '16'	Taylor Atkinson (b) (4)	06 Dec 2020 21:06:51

**US3902015**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:47:48
User entered 'breaths/min'	System	06 Dec 2020 21:06:51

US3902015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:47:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:51:05
User entered '111'	Taylor Atkinson (b) (4)	06 Dec 2020 21:06:51

US3902015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:47:48
User entered 'mmHg'	System	06 Dec 2020 21:06:51

US3902015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:47:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:51:05
User entered '68'	Taylor Atkinson (b) (4)	06 Dec 2020 21:06:51



**US3902015**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:47:48
User entered 'mmHg'	System	06 Dec 2020 21:06:51

**US3902015**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:47:48

US3902015

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:47:48

US3902015

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:40:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:48:00
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:51:23
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	06 Dec 2020 21:07:10

US3902015

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:40:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:48:00
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:51:23
User entered '30 Nov 2020'	Taylor Atkinson (b) (4)	06 Dec 2020 21:07:10

US3902015

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:40:59

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:48:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:51:41
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	06 Dec 2020 21:07:22

US3902015

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:40:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:48:06
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:51:41
User entered '30 Nov 2020'	Taylor Atkinson (b) (4)	06 Dec 2020 21:07:22

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:40:59**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	27 Feb 2021 17:34:47



US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:40:59

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '4 Feb 2021' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	02 Mar 2021 14:47:52
User entered '19 Feb 2021'	Bram Swarr (b) (4)	27 Feb 2021 17:34:47

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:40:59**

[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 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Clinic (Clinic)'	Bram Swarr (b) (4)	27 Feb 2021 17:34:47

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:40:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered 'UNBLND_DECIDE'	System	27 Feb 2021 17:34:47

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:40:59

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '4 Feb 2021'	Bram Swarr (b) (4)	05 Feb 2021 18:58:30

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:40:59**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:20:49

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:40:59

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	05 Feb 2021 18:58:30

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:40:59**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:20:49

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:40:59

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '4 Feb 2021'	Bram Swarr (b) (4)	05 Feb 2021 18:58:30



US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:40:59

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Placebo (Placebo)'	Bram Swarr (b) (4)	05 Feb 2021 18:58:30

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:40:59**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Placebo (Placebo)'	Bram Swarr (b) (4)	05 Feb 2021 18:58:30

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:40:59**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Placebo (Placebo)'	Bram Swarr (b) (4)	05 Feb 2021 18:58:30

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:40:59

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	05 Feb 2021 18:58:30

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:40:59**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered '1'	System	05 Feb 2021 18:58:30

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:40:59**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered 'I'	System	05 Feb 2021 18:58:30

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:40:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '66' in	Bram Swarr (b) (4)	27 Feb 2021 17:43:23

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:40:59

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System).	System	27 Feb 2021 17:44:09
Query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' answered by data change (Site from System).	System	27 Feb 2021 17:44:09
User entered '270' lb reason for change: Data Entry Error	Bram Swarr (b) (4)	27 Feb 2021 17:44:09
User opened query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System).	System	27 Feb 2021 17:43:23
User entered '27' lb	Bram Swarr (b) (4)	27 Feb 2021 17:43:23



**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 12 Aug 2021 13:40:59**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered '43.67026'	System	27 Feb 2021 17:44:09
User entered '4.36703'	System	27 Feb 2021 17:43:23
DataPoint set to visible.	System	05 Feb 2021 18:58:30

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:40:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '66' in	Bram Swarr (b) (4)	27 Feb 2021 17:43:23

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:40:59

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System).	System	27 Feb 2021 17:44:09
Query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' answered by data change (Site from System).	System	27 Feb 2021 17:44:09
User entered '270' lb reason for change: Data Entry Error	Bram Swarr (b) (4)	27 Feb 2021 17:44:09
User opened query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System).	System	27 Feb 2021 17:43:23
User entered '27' lb	Bram Swarr (b) (4)	27 Feb 2021 17:43:23

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 12 Aug 2021 13:40:59**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered '43.67026'	System	27 Feb 2021 17:44:09
User entered '4.36703'	System	27 Feb 2021 17:43:23
DataPoint set to visible.	System	05 Feb 2021 18:58:30

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User accepted default value 'Pre-Dose (PREDOSE)'	Bram Swarr (b) (4)	27 Feb 2021 17:43:23

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	27 Feb 2021 17:43:23

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '19 Feb 2021'	Bram Swarr (b) (4)	27 Feb 2021 17:43:23

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:40:59**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '13:12'	Bram Swarr (b) (4)	27 Feb 2021 17:43:23



**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered '19 Feb 2021 13:12'	System	27 Feb 2021 17:43:23

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '97.6' F	Bram Swarr (b) (4)	27 Feb 2021 17:43:23

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Oral (Oral)'	Bram Swarr (b) (4)	27 Feb 2021 17:43:23

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:40:59**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Bram Swarr (b) (4)	27 Feb 2021 17:43:23

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '78'	Bram Swarr (b) (4)	27 Feb 2021 17:43:23

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered 'bpm'	System	27 Feb 2021 17:43:23

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '16'	Bram Swarr (b) (4)	27 Feb 2021 17:43:23

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered 'breaths/min'	System	27 Feb 2021 17:43:23



US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '122'	Bram Swarr (b) (4)	27 Feb 2021 17:43:23

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered 'mmHg'	System	27 Feb 2021 17:43:23

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '73'	Bram Swarr (b) (4)	27 Feb 2021 17:43:23

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered 'mmHg'	System	27 Feb 2021 17:43:23

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 12 Aug 2021 13:40:59**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '66' in	Bram Swarr (b) (4)	27 Feb 2021 17:43:23

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:40:59

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System).	System	27 Feb 2021 17:44:09
Query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' answered by data change (Site from System).	System	27 Feb 2021 17:44:09
User entered '270' lb reason for change: Data Entry Error	Bram Swarr (b) (4)	27 Feb 2021 17:44:09
User opened query 'Weight reported is out of range <= 30kg (66lbs) or >= 181.818kg (400lbs). Please reconcile.' (Site from System).	System	27 Feb 2021 17:43:23
User entered '27' lb	Bram Swarr (b) (4)	27 Feb 2021 17:43:23

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 12 Aug 2021 13:40:59**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered '43.67026'	System	27 Feb 2021 17:44:09
User entered '4.36703'	System	27 Feb 2021 17:43:23
DataPoint set to visible.	System	05 Feb 2021 18:58:30

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User accepted default value 'Post-Dose (POSTDOSE)'	Bram Swarr (b) (4)	27 Feb 2021 17:43:23



US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	27 Feb 2021 17:43:23

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '19 Feb 2021'	Bram Swarr (b) (4)	27 Feb 2021 17:43:23

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '14:32'	Bram Swarr (b) (4)	27 Feb 2021 17:43:23

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered '19 Feb 2021 14:32'	System	27 Feb 2021 17:43:23

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '97.9' F	Bram Swarr (b) (4)	27 Feb 2021 17:43:23

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Oral (Oral)'	Bram Swarr (b) (4)	27 Feb 2021 17:43:23

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Bram Swarr (b) (4)	27 Feb 2021 17:43:23

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '72'	Bram Swarr (b) (4)	27 Feb 2021 17:43:23



**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered 'bpm'	System	27 Feb 2021 17:43:23

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '14'	Bram Swarr (b) (4)	27 Feb 2021 17:43:23

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered 'breaths/min'	System	27 Feb 2021 17:43:23

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '118'	Bram Swarr (b) (4)	27 Feb 2021 17:43:23

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered 'mmHg'	System	27 Feb 2021 17:43:23

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '70'	Bram Swarr (b) (4)	27 Feb 2021 17:43:23

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered 'mmHg'	System	27 Feb 2021 17:43:23

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:40:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'No (N)'	Bram Swarr (b) (4)	27 Feb 2021 17:40:10



US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:40:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Bram Swarr (b) (4)	27 Feb 2021 17:40:10

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:40:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	27 Feb 2021 17:42:27

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:40:59**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Bram Swarr (b) (4)	27 Feb 2021 17:42:27

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:40:59

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Bram Swarr (b) (4)	27 Feb 2021 17:42:27

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:40:59

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered 'mRNA-1273'	System	27 Feb 2021 17:42:27
DataPoint set to visible.	System	05 Feb 2021 18:58:30

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:40:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '19 Feb 2021'	Bram Swarr (b) (4)	27 Feb 2021 17:42:27

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:40:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '14:00'	Bram Swarr (b) (4)	27 Feb 2021 17:42:27

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:40:59**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered '19 Feb 2021 14:00'	System	27 Feb 2021 17:42:27



US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:40:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Left Arm (LEFT ARM)'	Bram Swarr (b) (4)	27 Feb 2021 17:42:27

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:40:59

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered 'ONCE'	System	27 Feb 2021 17:42:27

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:40:59**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered 'INTRAMUSCULAR'	System	27 Feb 2021 17:42:27

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:40:59**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	05 Feb 2021 18:58:51

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:40:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'The Collection Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System).	System	02 Mar 2021 14:47:52
User opened query 'The Collection Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System).	System	27 Feb 2021 17:34:47
User entered '4 Feb 2021'	Bram Swarr (b) (4)	05 Feb 2021 18:58:51

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:40:59**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '12:33'	Bram Swarr (b) (4)	05 Feb 2021 18:58:51

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:40:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered '4 Feb 2021 12:33'	System	05 Feb 2021 18:58:51

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 12 Aug 2021 13:40:59**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	05 Feb 2021 18:59:19



US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:40:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '4 Feb 2021'	Bram Swarr (b) (4)	05 Feb 2021 18:59:19

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 12 Aug 2021 13:40:59**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '12:35'	Bram Swarr (b) (4)	05 Feb 2021 18:59:19

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 12 Aug 2021 13:40:59**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered '4 Feb 2021 12:35'	System	05 Feb 2021 18:59:19

US3902015

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	05 Feb 2021 19:02:12

**US3902015**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:40:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered '1'	System	05 Feb 2021 19:02:12

**US3902015**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	27 Feb 2021 17:45:16

**US3902015**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '26 Feb 2021'	Bram Swarr (b) (4)	27 Feb 2021 17:45:16

**US3902015**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Contact Made (CONTACT MADE)'	Bram Swarr (b) (4)	27 Feb 2021 17:45:16



US3902015

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:40:59

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	Bram Swarr (b) (4)	27 Feb 2021 17:45:16

US3902015

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:40:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	Bram Swarr (b) (4)	27 Feb 2021 17:45:25

**US3902015**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:40:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered 'I'	System	27 Feb 2021 17:45:25

**US3902015**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:40:59**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered 'I'	System	27 Feb 2021 17:45:25
DataPoint set to visible.	System	27 Feb 2021 17:45:25

**US3902015**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:40:59**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Mar 2021 18:46:33

US3902015

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:40:59

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '16 Mar 2021'	(b) (4), (b) (6)	26 Mar 2021 18:46:33

**US3902015**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:40:59**

[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 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Mar 2021 18:46:33

**US3902015**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:40:59**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered 'OLD29'	System	26 Mar 2021 18:46:33



**US3902015**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	26 Mar 2021 18:49:03

US3902015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Mar 2021 18:49:03

**US3902015**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '16 Mar 2021'	(b) (4), (b) (6)	26 Mar 2021 18:49:03

**US3902015**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:40:59**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '09:48'	(b) (4), (b) (6)	26 Mar 2021 18:49:03

**US3902015**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered '16 Mar 2021 09:48'	System	26 Mar 2021 18:49:03

**US3902015**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '97.9' F	(b) (4), (b) (6)	26 Mar 2021 18:49:03

**US3902015**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Oral (Oral)'	(b) (4), (b) (6)	26 Mar 2021 18:49:03

**US3902015**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:40:59**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 18:49:03



**US3902015**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '72'	(b) (4), (b) (6)	26 Mar 2021 18:49:03

**US3902015**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered 'bpm'	System	26 Mar 2021 18:49:03

US3902015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '16'	(b) (4), (b) (6)	26 Mar 2021 18:49:03

**US3902015**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered 'breaths/min'	System	26 Mar 2021 18:49:03

**US3902015**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '142'	(b) (4), (b) (6)	26 Mar 2021 18:49:03

**US3902015**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered 'mmHg'	System	26 Mar 2021 18:49:03

US3902015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:40:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '92'	(b) (4), (b) (6)	26 Mar 2021 18:49:03

**US3902015**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered 'mmHg'	System	26 Mar 2021 18:49:03



**US3902015**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	26 Mar 2021 18:49:03

US3902015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Mar 2021 18:49:03

US3902015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '16 Mar 2021'	(b) (4), (b) (6)	26 Mar 2021 18:49:03

**US3902015**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:40:59**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '11:38'	(b) (4), (b) (6)	26 Mar 2021 18:49:03

**US3902015**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered '16 Mar 2021 11:38'	System	26 Mar 2021 18:49:03

US3902015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '97.3' F	(b) (4), (b) (6)	26 Mar 2021 18:49:03

**US3902015**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Oral (Oral)'	(b) (4), (b) (6)	26 Mar 2021 18:49:03

**US3902015**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:40:59**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 18:49:03



**US3902015**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '68'	(b) (4), (b) (6)	26 Mar 2021 18:49:03

**US3902015**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered 'bpm'	System	26 Mar 2021 18:49:03

US3902015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '16'	(b) (4), (b) (6)	26 Mar 2021 18:49:03

**US3902015**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered 'breaths/min'	System	26 Mar 2021 18:49:03

US3902015

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:40:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '145'	(b) (4), (b) (6)	26 Mar 2021 18:49:03

**US3902015**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered 'mmHg'	System	26 Mar 2021 18:49:03

**US3902015**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '94'	(b) (4), (b) (6)	26 Mar 2021 18:49:03

**US3902015**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered 'mmHg'	System	26 Mar 2021 18:49:03



US3902015

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:40:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'No (N)'	(b) (4), (b) (6)	26 Mar 2021 18:49:18

US3902015

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:40:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 18:49:18

**US3902015**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:40:59**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Mar 2021 18:50:05

**US3902015**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:40:59**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 18:50:05

US3902015

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:40:59

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 18:50:05

**US3902015**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:40:59**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered 'mRNA-1273'	System	26 Mar 2021 18:50:05
DataPoint set to visible.	System	27 Feb 2021 17:45:25

US3902015

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:40:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '16 Mar 2021'	(b) (4), (b) (6)	26 Mar 2021 18:50:05

**US3902015**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:40:59**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '11:00'	(b) (4), (b) (6)	26 Mar 2021 18:50:05



**US3902015**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:40:59**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered '16 Mar 2021 11:00'	System	26 Mar 2021 18:50:05

US3902015

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:40:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	26 Mar 2021 18:50:05

**US3902015**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:40:59**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered 'ONCE'	System	26 Mar 2021 18:50:05

**US3902015**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:40:59**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered 'INTRAMUSCULAR'	System	26 Mar 2021 18:50:05

**US3902015**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:40:59**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Mar 2021 18:50:41

**US3902015**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:40:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered 'I'	System	26 Mar 2021 18:50:41

**US3902015**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Mar 2021 18:52:43

**US3902015**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '23 Mar 2021'	(b) (4), (b) (6)	26 Mar 2021 18:52:43



**US3902015**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	26 Mar 2021 18:52:43

**US3902015**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:40:59**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 18:52:43

**US3902015**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:40:59**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Mar 2021 18:52:47

**US3902015**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:40:59**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:16:48
User entered 'I'	System	26 Mar 2021 18:52:47

**US3902015**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:40:59**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	23 Apr 2021 17:08:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Apr 2021 18:49:43

**US3902015**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:40:59**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	23 Apr 2021 17:08:39
User entered '13 Apr 2021'	(b) (4), (b) (6)	17 Apr 2021 18:49:43

US3902015

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:40:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	23 Apr 2021 17:08:39
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	17 Apr 2021 18:49:43

**US3902015**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:40:59**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	17 Apr 2021 18:49:43



US3902015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	23 Apr 2021 17:08:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Apr 2021 18:50:10

US3902015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	23 Apr 2021 17:08:39
User entered '13 Apr 2021'	(b) (4), (b) (6)	17 Apr 2021 18:50:10

**US3902015**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	23 Apr 2021 17:08:39
User entered '09:20'	(b) (4), (b) (6)	17 Apr 2021 18:50:10

**US3902015**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Apr 2021 09:20'	System	17 Apr 2021 18:50:10

**US3902015**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

**Temperature (xxx.x)**

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	23 Apr 2021 17:08:39
User entered '97.3' F	(b) (4), (b) (6)	17 Apr 2021 18:50:10

**US3902015**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	23 Apr 2021 17:08:39
User entered 'Oral (Oral)'	(b) (4), (b) (6)	17 Apr 2021 18:50:10

**US3902015**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	23 Apr 2021 17:08:39
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 18:50:10

**US3902015**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	23 Apr 2021 17:08:39
User entered '66'	(b) (4), (b) (6)	17 Apr 2021 18:50:10



**US3902015**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Apr 2021 18:50:10

US3902015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	23 Apr 2021 17:08:39
User entered '14'	(b) (4), (b) (6)	17 Apr 2021 18:50:10

**US3902015**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Apr 2021 18:50:10

US3902015

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:40:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	23 Apr 2021 17:08:39
User entered '134'	(b) (4), (b) (6)	17 Apr 2021 18:50:10

**US3902015**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Apr 2021 18:50:10

**US3902015**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	23 Apr 2021 17:08:39
User entered '86'	(b) (4), (b) (6)	17 Apr 2021 18:50:10

**US3902015**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:40:59**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Apr 2021 18:50:10

US3902015

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:40:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	23 Apr 2021 17:08:39
User entered 'No (N)'	(b) (4), (b) (6)	17 Apr 2021 18:50:16



US3902015

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:40:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	23 Apr 2021 17:08:39
User entered empty.	(b) (4), (b) (6)	17 Apr 2021 18:50:16

US3902015

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:40:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	23 Apr 2021 17:08:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Apr 2021 18:50:33

US3902015

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:40:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	23 Apr 2021 17:08:39
User entered '13 Apr 2021'	(b) (4), (b) (6)	17 Apr 2021 18:50:33

**US3902015**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:40:59**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	23 Apr 2021 17:08:39
User entered '09:51'	(b) (4), (b) (6)	17 Apr 2021 18:50:33

**US3902015**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:40:59**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Apr 2021 09:51'	System	17 Apr 2021 18:50:33

**US3902015**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 12 Aug 2021 13:40:59**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:17:29
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:04:32
User entered 'Yes (Y)'	Bram Swarr (b) (4)	27 Oct 2020 20:15:14

**US3902015**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:40:59**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:31
User entered	System	04 Nov 2020 15:53:26
'USA-US210-2020-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	04 Nov 2020 15:53:26

US3902015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:59

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 15:19:03
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 20:19:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 20:19:03
User closed query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. ' (Site from System).	System	23 Nov 2020 19:48:42
Query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. ' answered with 'updated' (Site from System).	Taylor Atkinson (b) (4)	23 Nov 2020 19:48:42
Data point term sent to Coder	System	23 Nov 2020 19:47:52
DataPoint Un-verified.	Taylor Atkinson (b) (4)	23 Nov 2020 19:47:48
	(b) (4)	
Coding entries removed.	Taylor Atkinson (b) (4)	23 Nov 2020 19:47:48
	(b) (4)	
User entered 'COVID-19' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	23 Nov 2020 19:47:48
User opened query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. ' (Site from System).	Coder Import (b) (4)	23 Nov 2020 12:24:10
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
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)	03 Nov 2020 19:32:29
	(b) (4)	



US3902015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:59

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	03 Nov 2020 19:32:29
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	03 Nov 2020 19:32:00
User entered 'Symptomatic COVID-19'	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
	(b) (4)	

US3902015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
	(b) (4), (b) (6)	
User closed query 'Please verify as CCG instructions note that this should be YES' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:57:00
Query 'Please verify as CCG instructions note that this should be YES' answered with 'Corrected - subject came into site for illness visit and was instructed to follow up with PCP' (Site from CRA).	Taylor Atkinson (b) (4)	04 Nov 2020 14:36:15
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	04 Nov 2020 14:35:38
	(b) (4)	
User opened query 'Please verify as CCG instructions note that this should be YES' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 13:31:20
	(b) (4)	
User entered 'No (N)'	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
	(b) (4)	

**US3902015**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
User entered 'No (N)'	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
	(b) (4)	

US3902015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
	(b) (4)	

US3902015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
User entered '26 Oct 2020'	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
	(b) (4)	

**US3902015**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
User entered empty.	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
	(b) (4)	

**US3902015**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:40:59**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 19:31:34

US3902015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:53:50
	(b) (4)	
DataPoint Un-verified.	Taylor Atkinson (b) (4)	07 Dec 2020 15:25:40
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	07 Dec 2020 15:25:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
	(b) (4)	
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
	(b) (4)	



US3902015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:53:52
	(b) (4)	
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	07 Dec 2020 15:26:29
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	07 Dec 2020 15:26:29
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	07 Dec 2020 15:25:40
DataPoint Un-verified.	Taylor Atkinson (b) (4)	07 Dec 2020 15:25:40
	(b) (4)	
User entered '10 Nov 2020' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	07 Dec 2020 15:25:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
	(b) (4)	
User entered empty.	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
	(b) (4)	

US3902015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:59

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
	(b) (4), (b) (6)	
User closed query 'Per MM: Please provide end date.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 08:26:07
Query 'Per MM: Please provide end date.' answered with 'Provided' (Site from DM).	Taylor Atkinson (b) (4)	07 Dec 2020 15:26:36
User closed query '. PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 15:44:05
User opened query 'Per MM: Please provide end date.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 18:47:46
Query '. PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'Will update end date when subject returns a negative test result - subject coming in for convalescent visit next week' (Site from Safety).	Taylor Atkinson (b) (4)	24 Nov 2020 17:00:29
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
User opened query '. PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 00:04:24
User entered empty.	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
	(b) (4)	

**US3902015**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:40:59**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 19:31:34

US3902015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:59

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
	(b) (4)	

US3902015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
User entered 'No (N)'	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
	(b) (4)	

**US3902015**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
User entered '0'	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
	(b) (4)	

**US3902015**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
User entered '0'	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
	(b) (4)	

**US3902015**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
User entered '0'	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
	(b) (4)	



US3902015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
User entered empty.	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
	(b) (4)	

US3902015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
User entered empty.	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
	(b) (4)	

US3902015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
User entered empty.	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
	(b) (4)	

US3902015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
User entered empty.	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
	(b) (4)	

US3902015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
User entered '0'	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
	(b) (4)	

US3902015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
User entered '0'	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
	(b) (4)	

US3902015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
User entered '0'	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
	(b) (4)	

US3902015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
User entered 'Not Related (NOT RELATED)'	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
	(b) (4)	



US3902015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
User entered 'Not Related (NOT RELATED)'	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
	(b) (4)	

**US3902015**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
User entered 'Not Applicable (NOT APPLICABLE)'	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
	(b) (4)	

**US3902015**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:40:59**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
User entered '0'	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
	(b) (4)	

US3902015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 15:34:36
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'Updated con meds as appropriate' (Site from DM).	Taylor Atkinson (b) (4)	06 Nov 2020 23:05:58
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 18:28:28
User entered 'I'	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
	(b) (4)	

**US3902015**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
User entered '0'	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
	(b) (4)	

US3902015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:59

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 18:53:58
	(b) (4)	
DataPoint Un-verified.	Taylor Atkinson (b) (4)	07 Dec 2020 15:26:29
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Taylor Atkinson (b) (4)	07 Dec 2020 15:26:29
Data Entry Error	(b) (4)	
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 15:44:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 15:19:14
	(b) (4)	
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Updated to recovering/resolving until subject returns a negative test' (Site from Safety).	Taylor Atkinson (b) (4)	23 Nov 2020 19:49:03
	(b) (4)	
DataPoint Un-verified.	Taylor Atkinson (b) (4)	23 Nov 2020 19:47:48
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Taylor Atkinson (b) (4)	23 Nov 2020 19:47:48
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
	(b) (4), (b) (6)	
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 00:04:58
	(b) (4), (b) (6)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
	(b) (4)	

US3902015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:43:44
User entered empty.	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
	(b) (4)	

US3902015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:40:59

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
	(b) (4), (b) (6)	10 Nov 2020 21:43:44
DataPoint Verified.	(b) (4), (b) (6)	08 Nov 2020 15:34:38
User closed query 'Per DM CLR: Narrative indicates that Naproxen Sodium was taken by the subject. However, there is no corresponding ConMed record that match this information. Please update to record the medication as appropriate. Otherwise, clarify.' (Site from DM).	Taylor Atkinson (b) (4)	06 Nov 2020 23:06:09
Query 'Per DM CLR: Narrative indicates that Naproxen Sodium was taken by the subject. However, there is no corresponding ConMed record that match this information. Please update to record the medication as appropriate. Otherwise, clarify.' answered with 'Updated con meds as appropriate' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 18:28:48
User opened query 'Per DM CLR: Narrative indicates that Naproxen Sodium was taken by the subject. However, there is no corresponding ConMed record that match this information. Please update to record the medication as appropriate. Otherwise, clarify.' (Site from DM).	Taylor Atkinson (b) (4)	03 Nov 2020 19:31:34
User entered 'Signs and Symptoms: Chills, Body Aches, Fatigue, Cough, Nasal Congestion, Mild Shortness of Breath, and Headache plus Myalgia and Fever. Investigations and Supporting Diagnostics: Postive COVID-19 PCR. Differential Diagnosis: Viral Syndrome. Course of Events: Symptoms -> testing -> PCP. Treatment/Response to Treatment: Naproxen Sodium -> PCP ongoing. Suspected Cause: Coronavirus. Other Comments: Evaluation by PCP pending'		



**US3902015**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Nov 2020 19:31:34

**US3902015**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 14:35:38
User entered '0'	System	03 Nov 2020 19:31:34

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:40:59

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:17:29
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:13:13
User entered 'Yes (Y)'	Bram Swarr (b) (4)	17 Sep 2020 16:56:10

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:59

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 17:00:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 17:00:45
Data point term sent to Coder	System	17 Sep 2020 16:59:20
User entered 'meloxicam'	Bram Swarr (b) (4)	17 Sep 2020 16:59:10

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'No (N)'	Bram Swarr (b) (4)	17 Sep 2020 16:59:10

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'back pain'	Bram Swarr (b) (4)	17 Sep 2020 16:59:10

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered '7.5'	Bram Swarr (b) (4)	17 Sep 2020 16:59:10

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'mg (mg)'	Bram Swarr (b) (4)	17 Sep 2020 16:59:10



US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered empty.	Bram Swarr (b) (4)	17 Sep 2020 16:59:10

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'every week (QS)'	Bram Swarr (b) (4)	17 Sep 2020 16:59:10

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered empty.	Bram Swarr (b) (4)	17 Sep 2020 16:59:10

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'Oral (ORAL)'	Bram Swarr (b) (4)	17 Sep 2020 16:59:10

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered empty.	Bram Swarr (b) (4)	17 Sep 2020 16:59:10

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'un UNK 2018'	Bram Swarr (b) (4)	17 Sep 2020 16:59:10

**US3902015**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered '0'	Bram Swarr (b) (4)	17 Sep 2020 16:59:10

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'Yes (Y)'	Bram Swarr (b) (4)	17 Sep 2020 16:59:10



US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	10 Nov 2020 23:19:06
User entered empty.	Bram Swarr (b) (4) [REDACTED]	17 Sep 2020 16:59:10

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:40:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'No (N)'	Bram Swarr (b) (4)	17 Sep 2020 16:59:10

**US3902015**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 16:59:10

**US3902015**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 16:59:10

**US3902015**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	17 Sep 2020 16:59:10

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:40:59

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 22:13:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 22:13:35
Data point term sent to Coder Coding entries removed.	System Taylor Atkinson (b) (4)	06 Nov 2020 22:48:06 06 Nov 2020 22:47:55
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 10:17:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 10:17:24
Data point term sent to Coder Coding entries removed.	System Bram Swarr (b) (4)	13 Oct 2020 18:33:09 13 Oct 2020 18:32:44
	(b) (4)	
User entered 'HYdrOCHLOROTHIAZIDE' reason for change: Data Entry Error	Bram Swarr (b) (4)	13 Oct 2020 18:32:44
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 23:02:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 23:02:02
Data point term sent to Coder	System	17 Sep 2020 17:00:23

US3902015

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'hydrochlorothiazide'	Bram Swarr (b) (4)	17 Sep 2020 16:59:47

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:40:59

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'No (N)'	Bram Swarr (b) (4)	17 Sep 2020 16:59:47



US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:40:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please update the indication to specify the laterality of LEG SWELLING (right, left, bilateral). Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).		08 Nov 2020 15:32:44
Query 'Per DM CLR: Please update the indication to specify the laterality of LEG SWELLING (right, left, bilateral). Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'Updated' (Site from DM).	Taylor Atkinson (b) (4)	06 Nov 2020 22:48:26
	(b) (4)	
User entered 'Bilateral Lower LEG SWELLING' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	06 Nov 2020 22:47:55
	(b) (4)	
User opened query 'Per DM CLR: Please update the indication to specify the laterality of LEG SWELLING (right, left, bilateral). Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:20:36
	(b) (4), (b) (6)	
Query 'Per DM CLR: Please update the indication to specify the laterality of LEG SWELLING. Please reconcile with the AE and Med History eCRFs as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:20:17
	(b) (4), (b) (6)	
User opened query 'Per DM CLR: Please update the indication to specify the laterality of LEG SWELLING. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:20:07
	(b) (4)	
User entered 'leg swelling'	Bram Swarr (b) (4)	17 Sep 2020 16:59:47
	(b) (4)	

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:40:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered '12.5'	Bram Swarr (b) (4)	17 Sep 2020 16:59:47

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:40:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'mg (mg)'	Bram Swarr (b) (4)	17 Sep 2020 16:59:47

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:40:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered empty.	Bram Swarr (b) (4)	17 Sep 2020 16:59:47

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:40:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'once daily (QD)'	Bram Swarr (b) (4)	17 Sep 2020 16:59:47

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:40:59

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered empty.	Bram Swarr (b) (4)	17 Sep 2020 16:59:47

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:40:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'Oral (ORAL)'	Bram Swarr (b) (4)	17 Sep 2020 16:59:47

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:40:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered empty.	Bram Swarr (b) (4)	17 Sep 2020 16:59:47



US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:40:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'un UNK 2019'	Bram Swarr (b) (4)	17 Sep 2020 16:59:47

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:40:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered '0'	Bram Swarr (b) (4)	17 Sep 2020 16:59:47

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:40:59

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'Yes (Y)'	Bram Swarr (b) (4)	17 Sep 2020 16:59:47

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:40:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered empty.	Bram Swarr (b) (4)	17 Sep 2020 16:59:47

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:40:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4) [REDACTED]	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	10 Nov 2020 23:19:06
User entered 'No (N)'	Bram Swarr (b) (4) [REDACTED]	17 Sep 2020 16:59:47

**US3902015**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 16:59:47

**US3902015**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 16:59:47

**US3902015**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Sep 2020 16:59:47



US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:40:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Nov 2020 22:13:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Nov 2020 22:13:36
Data point term sent to Coder Coding entries removed.	System Taylor Atkinson (b) (4)	06 Nov 2020 22:55:15 06 Nov 2020 22:54:49
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 17:01:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 17:01:36
Data point term sent to Coder User entered 'cyclobenzaprine'	System Bram Swarr (b) (4)	17 Sep 2020 17:00:23 17 Sep 2020 17:00:21

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:40:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'No (N)'	Bram Swarr (b) (4)	17 Sep 2020 17:00:21

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:40:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User closed query 'Per DM CLR: Please update the indication to reflect the location/type of MUSCLE SPASMS. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 15:32:57
Query 'Per DM CLR: Please update the indication to reflect the location/type of MUSCLE SPASMS. Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'Updated to reflect med hx' (Site from DM).	Taylor Atkinson (b) (4)	06 Nov 2020 22:55:00
User entered 'MUSCLE SPASMS in back' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 22:54:49
User opened query 'Per DM CLR: Please update the indication to reflect the location/type of MUSCLE SPASMS. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:22:50
User entered 'muscle spasms'	Bram Swarr (b) (4)	17 Sep 2020 17:00:21

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:40:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered '10'	Bram Swarr (b) (4)	17 Sep 2020 17:00:21

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:40:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'mg (mg)'	Bram Swarr (b) (4)	17 Sep 2020 17:00:21

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:40:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered empty.	Bram Swarr (b) (4)	17 Sep 2020 17:00:21

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:40:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'once daily (QD)'	Bram Swarr (b) (4)	17 Sep 2020 17:00:21

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:40:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered empty.	Bram Swarr (b) (4)	17 Sep 2020 17:00:21



**US3902015**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:40:59**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'Oral (ORAL)'	Bram Swarr (b) (4)	17 Sep 2020 17:00:21

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:40:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered empty.	Bram Swarr (b) (4)	17 Sep 2020 17:00:21

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:40:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'un UNK 2016'	Bram Swarr (b) (4)	17 Sep 2020 17:00:21

**US3902015**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:40:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered '0'	Bram Swarr (b) (4)	17 Sep 2020 17:00:21

**US3902015**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:40:59**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'No (N)' reason for change: Data Entry Error	Bram Swarr (b) (4)	13 Oct 2020 18:34:06
User entered 'Yes (Y)'	Bram Swarr (b) (4)	17 Sep 2020 17:00:21

**US3902015**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:40:59**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered '02 Oct 2020' reason for change: Data Entry Error	Bram Swarr (b) (4)	13 Oct 2020 18:34:06
User entered empty.	Bram Swarr (b) (4)	17 Sep 2020 17:00:21

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:40:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'No (N)'	Bram Swarr (b) (4)	17 Sep 2020 17:00:21

**US3902015**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:40:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User entered '1'	System	17 Sep 2020 17:00:21



US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:40:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User entered '1'	System	17 Sep 2020 17:00:21

US3902015

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:40:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User entered '804 (804)'	System	17 Sep 2020 17:00:21

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:40:59

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: BACLOFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Nov 2020 22:14:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Nov 2020 22:14:37
User closed query 'Per DM CLR: Note, this Con Med was added. Please clarify if there was a WORSENING of the Medical History condition requiring an additional medication. If yes, please add the applicable AE entry or explain the reason for additional in regimen' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 15:33:15
Query 'Per DM CLR: Note, this Con Med was added. Please clarify if there was a WORSENING of the Medical History condition requiring an additional medication. If yes, please add the applicable AE entry or explain the reason for additional in regimen' answered with 'Subject states the med is to help stabilize the spasms during work, not for the worsening of the condition' (Site from DM).	Taylor Atkinson (b) (4)	06 Nov 2020 22:59:08
Data point term sent to Coder Coding entries removed.	System	06 Nov 2020 22:56:16
	Taylor Atkinson (b) (4)	06 Nov 2020 22:55:22
User opened query 'Per DM CLR: Note, this Con Med was added. Please clarify if there was a WORSENING of the Medical History condition requiring an additional medication. If yes, please add the applicable AE entry or explain the reason for additional in regimen' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:24:10

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:40:59

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: BACLOFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 18:34:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 18:34:55
Data point term sent to Coder	System	13 Oct 2020 18:34:10
User entered 'baclofen'	Bram Swarr (b) (4) (b) (4)	13 Oct 2020 18:33:40

**US3902015**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:40:59**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'No (N)'	Bram Swarr (b) (4)	13 Oct 2020 18:33:40

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:40:59

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'Per DM CLR: this Con Med was added on 03-Oct-20. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 09:02:46
Query 'Per DM CLR: this Con Med was added on 03-Oct-20. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'As per subject, the condition did not worsen. Their PCP wrote it prophylactically because subject was going back to work' (Site from DM).	Taylor Atkinson (b) (4)	06 Dec 2020 21:03:49
User opened query 'Per DM CLR: this Con Med was added on 03-Oct-20. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 06:44:49
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'MUSCLE SPASMS in back' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	06 Nov 2020 22:55:22
Query 'Per DM CLR: Note, this Con Med was added. Please clarify if there was a WORSENING of the Medical History condition requiring an additional medication. If yes, please add the applicable AE entry or explain the reason for additional in regimen. ' canceled (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:24:06
User opened query 'Per DM CLR: Note, this Con Med was added. Please clarify if there was a WORSENING of the Medical History condition requiring an additional medication. If yes, please add the applicable AE entry or explain the reason for additional in regimen. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:23:31

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2445 of 2553

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:40:59

[Indication](#)

Audit	User	Time (GMT)
User entered 'muscle spasms'	Bram Swarr (b) (4)	13 Oct 2020 18:33:40

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:40:59

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered '5'	Bram Swarr (b) (4)	13 Oct 2020 18:33:40



US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:40:59

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'mg (mg)'	Bram Swarr (b) (4)	13 Oct 2020 18:33:40

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:40:59

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered empty.	Bram Swarr (b) (4)	13 Oct 2020 18:33:40

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:40:59

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'three times daily (TID)'	Bram Swarr (b) (4)	13 Oct 2020 18:33:40

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:40:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered empty.	Bram Swarr (b) (4)	13 Oct 2020 18:33:40

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:40:59

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'Oral (ORAL)'	Bram Swarr (b) (4)	13 Oct 2020 18:33:40

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:40:59

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered empty.	Bram Swarr (b) (4)	13 Oct 2020 18:33:40

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:40:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered '03 Oct 2020'	Bram Swarr (b) (4)	13 Oct 2020 18:33:40

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:40:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered '0'	Bram Swarr (b) (4)	13 Oct 2020 18:33:40



**US3902015**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:40:59**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'Yes (Y)'	Bram Swarr (b) (4)	13 Oct 2020 18:33:40

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:40:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered empty.	Bram Swarr (b) (4)	13 Oct 2020 18:33:40

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:40:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'No (N)'	Bram Swarr (b) (4)	13 Oct 2020 18:33:40

**US3902015**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:40:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Oct 2020 18:33:40

**US3902015**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:40:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 18:33:40

**US3902015**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:40:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 18:33:40

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:40:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 07:18:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 07:18:28
Data point term sent to Coder	System	06 Nov 2020 23:01:27
User entered 'Naproxen Sodium'	Taylor Atkinson (b) (4)	06 Nov 2020 23:01:24

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:40:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'No (N)'	Taylor Atkinson (b) (4)	06 Nov 2020 23:01:24



US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:40:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'Symptomatic COVID-19'	Taylor Atkinson (b) (4)	06 Nov 2020 23:01:24

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:40:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered '220'	Taylor Atkinson (b) (4)	06 Nov 2020 23:01:24

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:40:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'mg (mg)'	Taylor Atkinson (b) (4)	06 Nov 2020 23:01:24

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:40:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered empty.	Taylor Atkinson (b) (4)	06 Nov 2020 23:01:24

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:40:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'as needed (PRN)'	Taylor Atkinson (b) (4)	06 Nov 2020 23:01:24

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:40:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered empty.	Taylor Atkinson (b) (4)	06 Nov 2020 23:01:24

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:40:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'Oral (ORAL)'	Taylor Atkinson (b) (4)	06 Nov 2020 23:01:24

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:40:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered empty.	Taylor Atkinson (b) (4)	06 Nov 2020 23:01:24



**US3902015**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:40:59**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered '27 Oct 2020'	Taylor Atkinson (b) (4)	06 Nov 2020 23:01:24

**US3902015**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:40:59**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered '0'	Taylor Atkinson (b) (4)	06 Nov 2020 23:01:24

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:40:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4), (b) (6)	27 Feb 2021 06:12:32
Query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' answered with 'updated' (Site from DM).	Taylor Atkinson (b) (4)	25 Feb 2021 23:13:00
DataPoint Un-verified.	Taylor Atkinson (b) (4)	25 Feb 2021 23:12:55
User entered 'No (N)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	25 Feb 2021 23:12:55
User opened query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4), (b) (6)	07 Feb 2021 14:01:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	06 Nov 2020 23:01:24

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:40:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Un-verified.	Taylor Atkinson (b) (4)	25 Feb 2021 23:12:55
User entered '10 Nov 2020' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	25 Feb 2021 23:12:55
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered empty.	Taylor Atkinson (b) (4)	06 Nov 2020 23:01:24

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:40:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:45
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'No (N)'	Taylor Atkinson (b) (4)	06 Nov 2020 23:01:24

**US3902015**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:40:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:45
User entered empty.	System	06 Nov 2020 23:01:24

**US3902015**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:40:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:45
User entered empty.	System	06 Nov 2020 23:01:24

**US3902015**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:40:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:45
User entered empty.	System	06 Nov 2020 23:01:24



US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:40:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL;PHENYLE PHRINE HYDROCHLORIDE, PRODUCTSYNONYM: THERAFLU COLD & COUGH NIGHTTIME - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 15:24:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 15:24:46
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
Data point term sent to Coder	System	10 Nov 2020 23:18:20
User closed query 'For coding purposes, references indicate different formulations for THERAFLU. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' (Site from System).	System	10 Nov 2020 23:18:12
Query 'For coding purposes, references indicate different formulations for THERAFLU. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' answered with 'Updated as per query' (Site from System).	Taylor Atkinson (b) (4)	10 Nov 2020 23:18:12
User entered 'THERAFLU [Acetaminophen/Diphenhydramine HCL/Phenylephrine HCL]' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	10 Nov 2020 23:18:04
User opened query 'For coding purposes, references indicate different formulations for THERAFLU. Please provide generic ingredients, complete, accurate trade name and update the term with your response ' (Site from System).	Coder Import (b) (4)	08 Nov 2020 22:15:36
Data point term sent to Coder	System	06 Nov 2020 23:03:29

US3902015

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:40:59**

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Theraflu'	Taylor Atkinson (b) (4) (b) (4)	06 Nov 2020 23:03:09

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:40:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'No (N)'	Taylor Atkinson (b) (4)	06 Nov 2020 23:03:09

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:40:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'Symptomatic COVID-19'	Taylor Atkinson (b) (4)	06 Nov 2020 23:03:09

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:40:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered '650/25/10' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	10 Nov 2020 23:18:04
User entered '2'	Taylor Atkinson (b) (4)	06 Nov 2020 23:03:09

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:40:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'mg (mg)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	10 Nov 2020 23:18:04
User entered 'capsule (CAPSULE)'	Taylor Atkinson (b) (4)	06 Nov 2020 23:03:09

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:40:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered empty.	Taylor Atkinson (b) (4)	06 Nov 2020 23:03:09

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:40:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'other (OTHER)'	Taylor Atkinson (b) (4)	06 Nov 2020 23:03:09



US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:40:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'every 4 hours'	Taylor Atkinson (b) (4)	06 Nov 2020 23:03:09

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:40:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'Oral (ORAL)'	Taylor Atkinson (b) (4)	06 Nov 2020 23:03:09

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:40:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered empty.	Taylor Atkinson (b) (4)	06 Nov 2020 23:03:09

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:40:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered '2 Nov 2020'	Taylor Atkinson (b) (4)	06 Nov 2020 23:03:09

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:40:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered '0'	Taylor Atkinson (b) (4)	06 Nov 2020 23:03:09

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:40:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User closed query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4), (b) (6)	27 Feb 2021 06:13:00
Query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' answered with 'Updated' (Site from DM).	Taylor Atkinson (b) (4)	25 Feb 2021 23:12:26
DataPoint Un-verified.	Taylor Atkinson (b) (4)	25 Feb 2021 23:11:48
User entered 'No (N)' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	25 Feb 2021 23:11:48
User opened query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update as appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4), (b) (6)	07 Feb 2021 14:01:45
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'Yes (Y)'	Taylor Atkinson (b) (4)	06 Nov 2020 23:03:09

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:40:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Un-verified.	Taylor Atkinson (b) (4)	25 Feb 2021 23:11:48
User entered '10 Nov 2020' reason for change: Data Entry Error	Taylor Atkinson (b) (4)	25 Feb 2021 23:11:48
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered empty.	Taylor Atkinson (b) (4)	06 Nov 2020 23:03:09

US3902015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:40:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:19:06
User entered 'No (N)'	Taylor Atkinson (b) (4)	06 Nov 2020 23:03:09



**US3902015**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:40:59**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User entered empty.	System	06 Nov 2020 23:03:09

**US3902015**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:40:59**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User entered empty.	System	06 Nov 2020 23:03:09

**US3902015**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:40:59**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User entered empty.	System	06 Nov 2020 23:03:09

US3902015

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 12 Aug 2021 13:40:59**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'No (N)'	Bram Swarr (b) (4)	02 Mar 2021 19:12:00

**US3902015**

**Folder: SAE USA-US210-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:40:59**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'USA-US210-2020-MRNA-1273-P301000002'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

Serious

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'No (N)'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'No (N)'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'No (N)'	System	04 Nov 2020 15:53:26



US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'No (N)'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'No (N)'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'No (N)'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'No (N)'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'Murray'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'Kimmel'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 15:44:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
User entered 'US'	System	04 Nov 2020 15:54:18

**US3902015**

**Folder: SAE USA-US210-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:40:59**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	01 Dec 2020 21:38:42
User entered '2'	System	01 Dec 2020 15:44:26
User entered '1'	System	04 Nov 2020 15:54:18



US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered	System	04 Nov 2020 15:53:26
'USA-US210-2020-MRNA-1273-P301000002'		

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

Serious

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'No (N)'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'No (N)'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'No (N)'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'No (N)'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'No (N)'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'No (N)'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'No (N)'	System	04 Nov 2020 15:53:26



US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'Murray'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'Kimmel'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 15:44:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
User entered 'US'	System	04 Nov 2020 15:54:18

**US3902015**

**Folder: SAE USA-US210-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:40:59**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	01 Dec 2020 21:38:42
User entered '2'	System	01 Dec 2020 15:44:26
User entered '1'	System	04 Nov 2020 15:54:18

**US3902015**

**Folder: SAE USA-US210-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (1)**

**Generated On: 12 Aug 2021 13:40:59**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
User entered '04/Nov/2020 10:54'	System	04 Nov 2020 15:54:18

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 12 Aug 2021 13:40:59

**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.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 15:44:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
User entered 'I'	(b) (4), (b) (6)	04 Nov 2020 15:54:18

**US3902015**

**Folder: SAE USA-US210-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:40:59**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'USA-US210-2020-MRNA-1273-P301000002'	System	04 Nov 2020 15:53:26

**US3902015**

**Folder: SAE USA-US210-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:40:59**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'No (N)'	System	04 Nov 2020 15:53:26



US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'No (N)'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'No (N)'	System	04 Nov 2020 15:53:26

**US3902015**

**Folder: SAE USA-US210-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:40:59**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'No (N)'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'No (N)'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'No (N)'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'No (N)'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'Murray'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'Kimmel'	System	04 Nov 2020 15:53:26



US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 15:44:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
User entered 'US'	System	04 Nov 2020 15:54:18

**US3902015**

**Folder: SAE USA-US210-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:40:59**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	01 Dec 2020 21:38:42
User entered '2'	System	01 Dec 2020 15:44:26
User entered '1'	System	04 Nov 2020 15:54:18

**US3902015**

**Folder: SAE USA-US210-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (2)**

**Generated On: 12 Aug 2021 13:40:59**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:39:03
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '01/Dec/2020 15:44'	System	01 Dec 2020 15:44:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 12 Aug 2021 13:40:59

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:39:03
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 21:38:31
Un-reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 15:44:26
DataPoint Un-verified.	(b) (4), (b) (6)	01 Dec 2020 15:44:26
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Dec 2020 15:44:26
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 15:44:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 15:54:18

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'USA-US210-2020-MRNA-1273-P301000002'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

Serious

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'No (N)'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'No (N)'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'No (N)'	System	04 Nov 2020 15:53:26



US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'No (N)'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'No (N)'	System	04 Nov 2020 15:53:26

**US3902015**

**Folder: SAE USA-US210-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:40:59**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'No (N)'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'No (N)'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'Murray'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:53:47
User entered 'Kimmel'	System	04 Nov 2020 15:53:26

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 12 Aug 2021 13:40:59

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 15:44:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:36:13
User entered 'US'	System	04 Nov 2020 15:54:18

**US3902015**

**Folder: SAE USA-US210-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 12 Aug 2021 13:40:59**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	01 Dec 2020 21:38:42
User entered '2'	System	01 Dec 2020 15:44:26
User entered '1'	System	04 Nov 2020 15:54:18



**US3902015**

**Folder: SAE USA-US210-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (3)**

**Generated On: 12 Aug 2021 13:40:59**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:39:03
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered '01/Dec/2020 21:38'	System	01 Dec 2020 21:38:42

US3902015

Folder: SAE USA-US210-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 12 Aug 2021 13:40:59

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:39:03
User signature succeeded.	Murray Kimmel (b) (4)	30 Mar 2021 18:10:39
User entered 'I'	(b) (4), (b) (6)	01 Dec 2020 21:38:42