

US3462076 (Prod: Crisor, LLC)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:51:48

All time stamps listed in this document are displayed in GMT

US3462076

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 19:39:09

Generated On: 11 Aug 2021 22:51:48

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[Participant ID](#)

US3462076

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

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US3462076

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:21:33

Generated On: 11 Aug 2021 22:51:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 01:21:32

Generated On: 11 Aug 2021 22:51:48

Date of Birth (MMM yyyy)	(b) (6) 1992
Age	28
Age Units	YEARS
Age (Derived)	28
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 01:21:32

Generated On: 11 Aug 2021 22:51:48

Date of Informed Consent ( <i>dd MMM yyyy</i> )	07 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 01:21:32

Generated On: 11 Aug 2021 22:51:48

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 01:21:32

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 01:21:32

Generated On: 11 Aug 2021 22:51:48

Condition	PERENNIAL ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 01:21:32

Generated On: 11 Aug 2021 22:51:48

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 01:21:32

Generated On: 11 Aug 2021 22:51:48

Condition	OCCASIONAL BODY PAIN
Start date (dd MMM yyyy)	UN JAN 2020
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 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:21:33

Generated On: 11 Aug 2021 22:51:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 AUG 2020
Time of assessment (00:00-23:59)	10:35 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 10:35
Height (xxx.x)	169.6 cm
Weight (xxx.x)	76.3 kg
BMI (xxx.x)	26.52607 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:21:32

Generated On: 11 Aug 2021 22:51:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 01:21:32

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Date of assessment (dd MMM yyyy) 07 AUG 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

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

If Partner medically sterile or Other, specify \_\_\_\_\_  
If Surgically sterile, date of surgery (dd MMM yyyy) \_\_\_\_\_  
Date of surgery unknown False  
If Post-menopausal, date of last menstruation (dd MMM yyyy) \_\_\_\_\_  
Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 01:21:32

Generated On: 11 Aug 2021 22:51:48

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	07 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:21:32

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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** True

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:21:32

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



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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:21:33

Generated On: 11 Aug 2021 22:51:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 01:21:33

Generated On: 11 Aug 2021 22:51:48

What was the date of randomization? (dd MMM yyyy) 07 AUG 2020

What was the participant's randomization number? 101997

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 01:21:33

Generated On: 11 Aug 2021 22:51:48

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 01:21:33

Generated On: 11 Aug 2021 22:51:48

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 AUG 2020
Time of assessment (00:00-23:59)	10:35 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 10:35
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:21:33

Generated On: 11 Aug 2021 22:51:48

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 AUG 2020
Time of assessment (00:00-23:59)	11:59 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 11:59
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:21:33

Generated On: 11 Aug 2021 22:51:48

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 06 Apr 2021 22:55:04

Generated On: 11 Aug 2021 22:51:48

Was the pregnancy test performed? Yes ☐  
No ☒

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

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_

Collection time \_\_\_\_\_

Collection date and time (derived) \_\_\_\_\_

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:21:33

Generated On: 11 Aug 2021 22:51:48

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) 07 AUG 2020

What was the treatment time? (00:00-23:59) 11:29 (24 HR)

Treatment Date and Time (derived) 07 AUG 2020 11:29

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

What was the frequency of the study treatment dosing? ONCE

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



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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:21:33

Generated On: 11 Aug 2021 22:51:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

07 AUG 2020

Collection time (00:00-23:59)

11:10 (24 HR)

Collection date and time (derived)

07 AUG 2020 11:10

US3462076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Mar 2021 19:05:27

Generated On: 11 Aug 2021 22:51:48

Collection date (dd MMM yyyy)			07 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:13	07 AUG 2020 11:13
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:21:33

Generated On: 11 Aug 2021 22:51:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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 AUG 2020 12:01

PC Open Date & Time

07 AUG 2020 11:49

PC Close Date & Time

07 AUG 2020 14:19

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

**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 98.3 °F

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

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

PC Time Stamp	07 AUG 2020 15:22
PC Open Date & Time	07 AUG 2020 15:14
PC Close Date & Time	08 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

08 AUG 2020 22:10

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.3 °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

09 AUG 2020 20:08

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:51:48

**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

99.9 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

10 AUG 2020 13:42

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59



US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	99.7 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	11 AUG 2020 12:04
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:51:48

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 17:03

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 12:03

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

**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

07 AUG 2020 12:01

PC Open Date & Time

07 AUG 2020 11:49

PC Close Date & Time

07 AUG 2020 14:19

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☒

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 15:24

PC Open Date & Time

07 AUG 2020 15:14

PC Close Date & Time

08 AUG 2020 11:59

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:51:48

**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

08 AUG 2020 22:11

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:51:48

**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

09 AUG 2020 20:09

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:51:48

**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

10 AUG 2020 13:42

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59



US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:51:48

**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

11 AUG 2020 12:04

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:51:48

**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

12 AUG 2020 17:03

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:51:48

**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

13 AUG 2020 12:03

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

**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 ☐

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 12:02
PC Open Date & Time	07 AUG 2020 11:49
PC Close Date & Time	07 AUG 2020 14:19

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

**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 ☐

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 15:26
PC Open Date & Time	07 AUG 2020 15:14
PC Close Date & Time	08 AUG 2020 11:59

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:51:48

**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 ☒



US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:51:48

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 22:12
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:51:48

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 ☒

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:51:48

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 20:09
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☒

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☒

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:51:48

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 13:43
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:51:48

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 ☒

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:51:48

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

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:51:48

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 ☒



US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:51:48

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 17:04
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:51:48

**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 ☒

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:51:48

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 12:03
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3462076

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:51:48

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	14 AUG 2020 12:08
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3462076

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 19:05:27

Generated On: 11 Aug 2021 22:51:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462076

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:21:32

Generated On: 11 Aug 2021 22:51:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462076

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:21:32

Generated On: 11 Aug 2021 22:51:48

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

PATIENT CONTACTED VIA  
ILLNESS VISIT CONTACT  
PHONE CALL BY PI

*If Contact Not Made, please provide Comments*

US3462076

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:21:32

Generated On: 11 Aug 2021 22:51:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3462076

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:21:32

Generated On: 11 Aug 2021 22:51:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462076

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:21:32

Generated On: 11 Aug 2021 22:51:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462076

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:21:34

Generated On: 11 Aug 2021 22:51:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3462076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 01:21:34

Generated On: 11 Aug 2021 22:51:48

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)	04 SEP 2020
Time of assessment (00:00-23:59)	10:40 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 10:40
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3462076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:21:34

Generated On: 11 Aug 2021 22:51:48

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)	04 SEP 2020
Time of assessment (00:00-23:59)	12:16 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 12:16
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3462076

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:21:34

Generated On: 11 Aug 2021 22:51:48

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.*

US3462076

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 01:21:34

Generated On: 11 Aug 2021 22:51:48

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	04 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3462076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:21:34

Generated On: 11 Aug 2021 22:51:48

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) 04 SEP 2020

What was the treatment time? (00:00-23:59) 11:45 (24 HR)

Treatment Date and Time (derived) 04 SEP 2020 11:45

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



US3462076

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:21:34

Generated On: 11 Aug 2021 22:51:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

04 SEP 2020

Collection time (00:00-23:59)

11:25 (24 HR)

Collection date and time (derived)

04 SEP 2020 11:25

US3462076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:21:33

Generated On: 11 Aug 2021 22:51:48

Collection date (dd MMM yyyy)			04 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:28	04 SEP 2020 11:28
Nasopharyngeal Swab 2	No		

US3462076

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:21:33

Generated On: 11 Aug 2021 22:51:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 12:18

PC Open Date & Time

04 SEP 2020 12:05

PC Close Date & Time

04 SEP 2020 14:35

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

**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 98.6 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 04 SEP 2020 19:39

PC Open Date & Time 04 SEP 2020 15:30

PC Close Date & Time 05 SEP 2020 11:59

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:51:48

**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 99.4 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 05 SEP 2020 20:32

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.7 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	True
PC Time Stamp	06 SEP 2020 20:55
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:51:48

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.3 °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

07 SEP 2020 13:09

---

PC Open Date & Time

07 SEP 2020 12:00

---

PC Close Date & Time

08 SEP 2020 11:59

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US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:51:48

**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

99.2 °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 12:02

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:51:48

**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

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 12:51

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

**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

04 SEP 2020 12:18

PC Open Date & Time

04 SEP 2020 12:05

PC Close Date & Time

04 SEP 2020 14:35

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 15:35

PC Open Date & Time

04 SEP 2020 15:30

PC Close Date & Time

05 SEP 2020 11:59

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

1

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

05 SEP 2020 12:00

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:51:48

**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

06 SEP 2020 20:41

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:51:48

**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

07 SEP 2020 13:09

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59



US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:51:48

**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

08 SEP 2020 12:01

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:51:48

**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

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:51:48

**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

10 SEP 2020 12:51

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

**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 ☐

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 12:19
PC Open Date & Time	04 SEP 2020 12:05
PC Close Date & Time	04 SEP 2020 14:35

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

**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 ☐

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 15:36
PC Open Date & Time	04 SEP 2020 15:30
PC Close Date & Time	05 SEP 2020 11:59

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☒

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

95 of 2303

EAB) (1725)



US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:51:48

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

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:51:48

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

97 of 2303

EAB) (1725)

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:51:48

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 20:41
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:51:48

**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 ☒

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:51:48

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 13:09
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:51:48

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

101 of 2303

EAB) (1725)

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:51:48

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 12:02
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:51:48

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 ☐



US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:51:48

Yes ☐

PC Time stamp

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:51:48

**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 ☒

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:51:48

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

US3462076

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

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 ☐

PC Time Stamp

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3462076

Folder: Diary Dose 2 (1)

Form: Headache\_Day(9)

Generated On: 11 Aug 2021 22:51:48

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**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

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 ☐

---

PC Time Stamp

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

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US3462076

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time Stamp

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3462076

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 11 Aug 2021 22:51:48

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time Stamp

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3462076

Folder: Diary Dose 2 (1)

Form: Chills\_Day(8)

Generated On: 11 Aug 2021 22:51:48

---

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of **CHILLS** you  
are experiencing

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

---

PC Open Date & Time

11 SEP 2020 12:00

---

PC Close Date & Time

12 SEP 2020 11:59

---

PC Time stamp

---



US3462076

Folder: Diary Dose 2 (1)

Form: Chills\_Day(9)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

PC Open Date & Time 12 SEP 2020 12:00

PC Close Date & Time 13 SEP 2020 11:59

PC Time stamp

US3462076

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:51:48

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

US3462076

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:51:48

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3462076

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:21:32

Generated On: 11 Aug 2021 22:51:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462076

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:21:32

Generated On: 11 Aug 2021 22:51:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462076

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:21:32

Generated On: 11 Aug 2021 22:51:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462076

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:21:32

Generated On: 11 Aug 2021 22:51:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462076

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:21:32

Generated On: 11 Aug 2021 22:51:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3462076

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:21:32

Generated On: 11 Aug 2021 22:51:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462076

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:21:34

Generated On: 11 Aug 2021 22:51:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3462076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:21:34

Generated On: 11 Aug 2021 22:51:48

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) \_\_\_\_\_

US3462076

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:21:34

Generated On: 11 Aug 2021 22:51:48

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.*

US3462076

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:21:34

Generated On: 11 Aug 2021 22:51:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

09 OCT 2020

Collection time (00:00-23:59)

12:20 (24 HR)

Collection date and time (derived)

09 OCT 2020 12:20

US3462076

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:21:34

Generated On: 11 Aug 2021 22:51:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 OCT 2020 00:01

Patient Cloud Close Date & Time

11 OCT 2020 23:59



US3462076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 OCT 2020 00:25:15

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3462076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 OCT 2020 00:01:53

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3462076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	True
Chills	False
Cough	True
Shortness of breath	True
Difficulty breathing	True
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	True
Runny nose	True
Nausea	False
Vomiting	True
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	04 NOV 2020 00:02:06
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

US3462076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3462076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 10:53:34

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59



US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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03 DEC 2020 23:59

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US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 DEC 2020 15:00:26

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 DEC 2020 00:01:25

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

24 DEC 2020 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 00:01:37

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**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

05 JAN 2021 14:32:14

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59



US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 JAN 2021 13:01:26

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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 <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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

[Patient Cloud Close Date & Time](#)

21 JAN 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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 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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

31 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

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US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>



**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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[Patient Cloud Open Date & Time](#)

07 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

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US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	False
Chills	True
Cough	False
Shortness of breath	True
Difficulty breathing	True
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	True
Nausea	True
Vomiting	True
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	14 FEB 2021 12:06:25
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 00:01:47

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**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

28 FEB 2021 01:48:39

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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 <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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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[Patient Cloud Close Date & Time](#)

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11 MAR 2021 23:59

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US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 MAR 2021 15:23:43

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**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

21 MAR 2021 00:01:28

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59



US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**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°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 ☐

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

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US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 APR 2021 00:22:17

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 00:30:34

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59



US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 271

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

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

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

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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="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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59



US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

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10 JUN 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**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 ☐

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59



US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

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04 JUL 2021 00:01

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08 JUL 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

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15 JUL 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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22 JUL 2021 23:59



US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**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°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 ☐

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**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 ☐

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

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05 AUG 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59



US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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02 SEP 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

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09 SEP 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59



US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

19 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

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US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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[Patient Cloud Open Date & Time](#)

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03 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 OCT 2021 23:59

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US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59



US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

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US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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[Patient Cloud Close Date & Time](#)

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25 NOV 2021 23:59

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US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59



US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**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°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 ☐

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

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US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

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 ☐

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

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20 JAN 2022 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**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°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 ☐

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

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23 JAN 2022 00:01

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27 JAN 2022 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

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US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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 <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"/>

**US3462076**

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

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**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

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06 FEB 2022 00:01

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10 FEB 2022 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**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 ☐

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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13 FEB 2022 00:01

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17 FEB 2022 23:59

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US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**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 ☐

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**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 ☐

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

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US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**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 ☐

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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17 MAR 2022 23:59

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US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**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 ☐

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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"/>

**US3462076**

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

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**Generated On: 11 Aug 2021 22:51:48**

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

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27 MAR 2022 00:01

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US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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

**US3462076**

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

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

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07 APR 2022 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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"/>

**US3462076**

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

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

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

Date and time of submission

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14 APR 2022 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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[Patient Cloud Close Date & Time](#)

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21 APR 2022 23:59

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US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

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 ☐

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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[Patient Cloud Open Date & Time](#)

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24 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 APR 2022 23:59

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US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 635

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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[Patient Cloud Open Date & Time](#)

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01 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 MAY 2022 23:59

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US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**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 ☐

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59



US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**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 ☐

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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 ☐

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

DAY 684

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59



US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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 <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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUL 2022 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**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 ☐

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

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17 JUL 2022 00:01

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21 JUL 2022 23:59



US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**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 ☐

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

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24 JUL 2022 00:01

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28 JUL 2022 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

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31 JUL 2022 00:01

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04 AUG 2022 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

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11 AUG 2022 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

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14 AUG 2022 00:01

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18 AUG 2022 23:59



US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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°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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

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25 AUG 2022 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

**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 ☐

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

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01 SEP 2022 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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

Date and time of submission

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08 SEP 2022 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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11 SEP 2022 00:01

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15 SEP 2022 23:59

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US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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22 SEP 2022 23:59

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US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

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**Generated On: 11 Aug 2021 22:51:48**

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

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

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25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

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US3462076

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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"/>

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

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[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

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US3462076

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:51:48

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 01:48:49

US3462076

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 19:39:10

Generated On: 11 Aug 2021 22:51:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462076

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 19:39:10

Generated On: 11 Aug 2021 22:51:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462076

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 22:06:48

Generated On: 11 Aug 2021 22:51:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462076

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 22:06:48

Generated On: 11 Aug 2021 22:51:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462076

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 22:06:48

Generated On: 11 Aug 2021 22:51:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3462076

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 22:06:48

Generated On: 11 Aug 2021 22:51:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462076

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 13:15:18

Generated On: 11 Aug 2021 22:51:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3462076

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 22:06:48

Generated On: 11 Aug 2021 22:51:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3462076

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 22:06:48

Generated On: 11 Aug 2021 22:51:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3462076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 19:03:59

Generated On: 11 Aug 2021 22:51:48

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) \_\_\_\_\_

US3462076

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 22:06:48

Generated On: 11 Aug 2021 22:51:48

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.*

US3462076

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 22:06:48

Generated On: 11 Aug 2021 22:51:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 MAR 2021

Collection time (00:00-23:59)

15:40 (24 HR)

Collection date and time (derived)

16 MAR 2021 15:40

US3462076

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 22:06:48

Generated On: 11 Aug 2021 22:51:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3462076**

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

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:51:48**

Was Contact Attempted? Yes ☐  
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

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

Comments

*If Contact Not Made, please provide Comments*

**US3462076**

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

**Form: Continuing**

**Generated On: 11 Aug 2021 22:51:48**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: COVID-19 Contact

Data signed: (b) (4) 19 Mar 2021 19:05:26

Generated On: 11 Aug 2021 22:51:48

Date of Contact	17 AUG 2020
Time of Contact	08:00
Date and Time of Contact (derived)	17 AUG 2020 08:00
Type of Contact	<div>Clinic Visit - Scheduled <input checked="" type="radio"/></div> <div>Clinical Visit - Unscheduled <input type="radio"/></div> <div>Safety Call <input type="radio"/></div> <div>Convalescent Tele-visit <input type="radio"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="radio"/></div> <div>No <input type="radio"/></div>

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

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"/>

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 AUG 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input 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 type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

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

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

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 ☐

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

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"/>

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 AUG 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	101.9 F	
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 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)

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

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 ☐

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

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"/>

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 AUG 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

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

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

Symptom Day

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

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	99.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

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



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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (5)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

Symptom Day

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

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Form: Symptom Log (5)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

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

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (6)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

Symptom Day

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

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Form: Symptom Log (6)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 AUG 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

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



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Form: Symptom Log (6)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

Symptom Day

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

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Form: Symptom Log (7)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 AUG 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

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

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

Symptom Day

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

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 AUG 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

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



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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 22 Apr 2021 16:08:14

Generated On: 11 Aug 2021 22:51:48

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 17 Aug 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 19 Feb 2021 19:39:09

Generated On: 11 Aug 2021 22:51:48

Date of Visit 17 AUG 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐ No ☒

Date of Test 17 AUG 2020

Type of Test Performed Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐ No ☒

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐ No ☐

COVID-19 Positive (CSA Programming Field Only) 0

**US3462076**

**Folder: Covid-19 Assessment 17 Aug 2020**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 11 Aug 2021 22:51:48**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 19 Mar 2021 19:05:26

Generated On: 11 Aug 2021 22:51:48

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	19 AUG 2020
Day 5	Yes	21 AUG 2020
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 19:05:27

Generated On: 11 Aug 2021 22:51:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Mar 2021 19:05:27

Generated On: 11 Aug 2021 22:51:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	09:00 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 09:00
Height (xxx.x)	169.6 cm
Weight (xxx.x)	76.3 kg
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 19:05:27

Generated On: 11 Aug 2021 22:51:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 AUG 2020

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

US3462076

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 19 Mar 2021 19:05:27

Generated On: 11 Aug 2021 22:51:48

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

17 AUG 2020



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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 19:39:10

Generated On: 11 Aug 2021 22:51:48

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

Visit date (dd MMM yyyy)	12 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
------------	---------------

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

Form: Unblinding

Data signed: (b) (4) 19 Mar 2021 19:05:27

Generated On: 11 Aug 2021 22:51:48

Date of updated informed consent (dd MMM yyyy) 12 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 12 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 19:39:10

Generated On: 11 Aug 2021 22:51:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 JAN 2021

Collection time (00:00-23:59)

14:13 (24 HR)

Collection date and time (derived)

12 JAN 2021 14:13

US3462076

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 19:39:10

Generated On: 11 Aug 2021 22:51:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 JAN 2021

Collection time (00:00 - 23:59)

14:02

Collection Date and Time (derived)

12 JAN 2021 14:02

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 19:39:09

Generated On: 11 Aug 2021 22:51:48

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 19:05:26

Generated On: 11 Aug 2021 22:51:48

AEID

Adverse event

RIGHT WRIST SPRAIN

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

07 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

22 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 19:05:26

Generated On: 11 Aug 2021 22:51:48

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Mar 2021 19:05:26

Generated On: 11 Aug 2021 22:51:48

AEID

Adverse event

UPPER RESPIRATORY TRACT  
INFECTION

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

15 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

21 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 19 Mar 2021 19:05:26

Generated On: 11 Aug 2021 22:51:48

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 19 Mar 2021 19:05:26

Generated On: 11 Aug 2021 22:51:48

AEID	
Adverse event	NAUSEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 19 Mar 2021 19:05:26

Generated On: 11 Aug 2021 22:51:48

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 19:39:09

Generated On: 11 Aug 2021 22:51:48

---

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

---

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

---

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 06 Apr 2021 14:33:21

Generated On: 11 Aug 2021 22:51:48

Name of Medication WOMENS COMPLETE VITAMIN

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☒  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 06 Apr 2021 14:33:21

Generated On: 11 Aug 2021 22:51:48

	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 MAY 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Apr 2021 14:33:21

Generated On: 11 Aug 2021 22:51:48

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication OCCASIONAL BODY PAIN

Dose per administration 325

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Apr 2021 14:33:21

Generated On: 11 Aug 2021 22:51:48

	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 JAN 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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 06 Apr 2021 14:33:21

Generated On: 11 Aug 2021 22:51:48

Name of Medication NEXPLANON IMPLANT

Prophylaxis Yes ☒  
No ☐

Indication BIRTH CONTROL

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify IMPLANT

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 YEARS

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☒  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 06 Apr 2021 14:33:21

Generated On: 11 Aug 2021 22:51:48

	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 AUG 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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 06 Apr 2021 14:33:21

Generated On: 11 Aug 2021 22:51:48

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication UPPER RESPIRATORY TRACT  
INFECTION

Dose per administration 500

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 06 Apr 2021 14:33:21

Generated On: 11 Aug 2021 22:51:48

	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)	17 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	18 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 06 Apr 2021 14:33:21

Generated On: 11 Aug 2021 22:51:48

Name of Medication TULANA

Prophylaxis Yes ☒  
No ☐

Indication BIRTH CONTROL

Dose per administration 0.3

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 06 Apr 2021 14:33:21

Generated On: 11 Aug 2021 22:51:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 07 SEP 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"/>

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 06 Apr 2021 14:33:21

Generated On: 11 Aug 2021 22:51:48

Name of Medication ONDANSETRON

Prophylaxis Yes ☐  
No ☒

Indication NAUSEA

Dose per administration 4

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 06 Apr 2021 14:33:21

Generated On: 11 Aug 2021 22:51:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 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)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 06 Apr 2021 14:33:21

Generated On: 11 Aug 2021 22:51:48

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication INJECTION SITE PAIN

Dose per administration 325

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 06 Apr 2021 14:33:21

Generated On: 11 Aug 2021 22:51:48

	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)		04 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 06 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

US3462076

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 19:39:09

Generated On: 11 Aug 2021 22:51:48

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3462076

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:51:48

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

US3462076

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:51:48

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 ☐

US3462076

Folder: SAE USA-US093-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 19 Feb 2021 19:39:10

Generated On: 11 Aug 2021 22:51:48

SAEID	USA-US093-2020-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	EDWARD
Investigator's Last Name	KERWIN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3462076

Folder: SAE USA-US093-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Feb 2021 19:39:10

Generated On: 11 Aug 2021 22:51:48

SAEID	USA-US093-2020-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	EDWARD
Investigator's Last Name	KERWIN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	09/SEP/2020 13:58
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

US3462076

Folder: SAE USA-US093-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Feb 2021 19:39:10

Generated On: 11 Aug 2021 22:51:48

SAEID	USA-US093-2020-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	EDWARD
Investigator's Last Name	KERWIN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	06/NOV/2020 20:04
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

US3462076 (Prod: Crisor, LLC)

**US3462076**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 22:51:48**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'US3462076'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:29:13

US3462076

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:51:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	07 Aug 2020 18:29:47

US3462076

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:51:48

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '07 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:29:14

US3462076

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:51:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Clinic (Clinic)'	Savannah Peterson (b) (4)	07 Aug 2020 18:29:47

**US3462076**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:51:48**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User entered 'SCRN'	System	07 Aug 2020 18:29:47

US3462076

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:48

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered (b) (6) 1992'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:29:15

US3462076

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:48

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '28'	Savannah Peterson (b) (4)	07 Aug 2020 18:30:00



**US3462076**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:51:48**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User entered 'YEARS'	System	07 Aug 2020 18:30:00

**US3462076**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:51:48**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User entered '28'	System	07 Aug 2020 18:30:17

**US3462076**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:51:48**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Female (F)'	Savannah Peterson (b) (4)	07 Aug 2020 18:30:00

US3462076

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:48

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Savannah Peterson (b) (4)	07 Aug 2020 18:30:00

**US3462076**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:51:48**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'I'	Savannah Peterson (b) (4)	07 Aug 2020 18:30:00

**US3462076**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:51:48**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '0'	Savannah Peterson (b) (4)	07 Aug 2020 18:30:00

US3462076

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:48

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '0'	Savannah Peterson (b) (4)	07 Aug 2020 18:30:00

US3462076

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:48

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '0'	Savannah Peterson (b) (4)	07 Aug 2020 18:30:00



**US3462076**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:51:48**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '0'	Savannah Peterson (b) (4)	07 Aug 2020 18:30:00

**US3462076**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:51:48**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '0'	Savannah Peterson (b) (4)	07 Aug 2020 18:30:00

US3462076

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:48

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty.	Savannah Peterson (b) (4)	07 Aug 2020 18:30:00

US3462076

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:48

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '0'	Savannah Peterson (b) (4)	07 Aug 2020 18:30:00

US3462076

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:51:48

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '0'	Savannah Peterson (b) (4)	07 Aug 2020 18:30:00

US3462076

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:51:48

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '07 Aug 2020'	Savannah Peterson (b) (4)	07 Aug 2020 18:30:17

**US3462076**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:51:48**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User entered 'Aug 2020'	System	07 Aug 2020 18:30:17

**US3462076**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:51:48**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User entered '2020'	System	07 Aug 2020 18:30:17



**US3462076**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:51:48**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Amendment 1 (1)'	Savannah Peterson (b) (4)	07 Aug 2020 18:30:17

US3462076

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:51:48

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	07 Aug 2020 18:30:17

US3462076

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:51:48

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty.	Savannah Peterson (b) (4)	07 Aug 2020 18:30:17

US3462076

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:51:48

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty.	Savannah Peterson (b) (4)	07 Aug 2020 18:30:17

US3462076

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:51:48

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'No (N)'	Savannah Peterson (b) (4)	07 Aug 2020 18:30:17

US3462076

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:51:48

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:29:14

**US3462076**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:51:48**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User entered 'I'	System	07 Aug 2020 18:30:24

US3462076

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:51:48

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	07 Aug 2020 18:30:24



US3462076

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:51:48

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:35:48

US3462076

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:51:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis perennial, LLT: Perennial allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 23:29:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 23:29:20
Data point term sent to Coder	System	10 Aug 2020 22:37:32
User entered 'PERENNIAL ALLERGIC RHINITIS'	Daniel Hamlin (b) (4)	10 Aug 2020 22:36:45

US3462076

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:51:48

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'UN UNK 2019'	Danuel Hamlin (b) (4)	10 Aug 2020 22:36:45

US3462076

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:51:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:36:45

US3462076

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:51:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:36:45

**US3462076**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:51:48**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:36:45

US3462076

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:51:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '0'	Danuel Hamlin (b) (4)	10 Aug 2020 22:36:45

**US3462076**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:51:48**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User entered 'Jan 2019'	System	10 Aug 2020 22:36:45



**US3462076**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:51:48**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User entered '2019'	System	10 Aug 2020 22:36:45

**US3462076**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:51:48**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User entered empty.	System	10 Aug 2020 22:36:45

**US3462076**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:51:48**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User entered empty.	System	10 Aug 2020 22:36:45

US3462076

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:51:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 23:29:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 23:29:22
Data point term sent to Coder	System	10 Aug 2020 22:37:32
User entered 'ECZEMA'	Danuel Hamlin (b) (4)	10 Aug 2020 22:37:08

US3462076

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:51:48

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'UN UNK 2017'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:37:08

US3462076

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:51:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:37:08

US3462076

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:51:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:37:08

US3462076

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:51:48

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:37:08



US3462076

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:51:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:37:08

**US3462076**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:51:48**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User entered 'Jan 2017'	System	10 Aug 2020 22:37:08

**US3462076**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:51:48**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User entered '2017'	System	10 Aug 2020 22:37:08

**US3462076**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:51:48**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User entered empty.	System	10 Aug 2020 22:37:08

**US3462076**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:51:48**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User entered empty.	System	10 Aug 2020 22:37:08

US3462076

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:51:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 12:58:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 12:58:17
Data point term sent to Coder	System	10 Aug 2020 22:37:33
User entered 'OCCASIONAL BODY PAIN'	Danuel Hamlin (b) (4)	10 Aug 2020 22:37:26

US3462076

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:51:48

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'UN Jan 2020'	Danuel Hamlin (b) (4)	10 Aug 2020 22:37:26

US3462076

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:51:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:37:26



US3462076

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:51:48

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:37:26

US3462076

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:51:48

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty.	Danuel Hamlin (b) (4)	10 Aug 2020 22:37:26

US3462076

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:51:48

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '0'	Danuel Hamlin (b) (4)	10 Aug 2020 22:37:26

**US3462076**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:51:48**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User entered 'Jan 2020'	System	10 Aug 2020 22:37:26

**US3462076**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:51:48**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User entered '2020'	System	10 Aug 2020 22:37:26

**US3462076**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:51:48**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User entered empty.	System	10 Aug 2020 22:37:26

**US3462076**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:51:48**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User entered empty.	System	10 Aug 2020 22:37:26

US3462076

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:39:00



US3462076

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '07 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:39:00

US3462076

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '10:35'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:39:00

**US3462076**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User entered '07 Aug 2020 10:35'	System	10 Aug 2020 22:39:00

US3462076

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '169.6' cm	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:39:00
DataPoint set to visible.	System	07 Aug 2020 18:30:24

US3462076

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '76.3' kg	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:39:00
DataPoint set to visible.	System	07 Aug 2020 18:30:24

US3462076

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
Amendment Manager: User entered '26.52607'	System	16 Sep 2020 23:47:38
User entered '26.5'	System	10 Aug 2020 22:39:00
DataPoint set to visible.	System	07 Aug 2020 18:30:24

US3462076

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User entered 'kg/m2'	System	10 Aug 2020 22:39:00
DataPoint set to visible.	System	07 Aug 2020 18:30:24

US3462076

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 21:05:29
User entered '98.4' F	Danuel Hamlin (b) (4)	10 Aug 2020 22:39:00



US3462076

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 21:05:29
User entered 'Oral (Oral)'	Danuel Hamlin (b) (4)	10 Aug 2020 22:39:00

US3462076

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:39:00

US3462076

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 21:05:29
User entered '75'	Danuel Hamlin (b) (4)	10 Aug 2020 22:39:00

**US3462076**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User entered 'bpm'	System	10 Aug 2020 22:39:00

US3462076

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 21:05:29
User entered '14'	Danuel Hamlin (b) (4)	10 Aug 2020 22:39:00

**US3462076**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User entered 'breaths/min'	System	10 Aug 2020 22:39:00

US3462076

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 21:05:29
User entered '104'	Danuel Hamlin (b) (4)	10 Aug 2020 22:39:00

**US3462076**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User entered 'mmHg'	System	10 Aug 2020 22:39:00



US3462076

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 21:05:29
User entered '70'	Danuel Hamlin (b) (4)	10 Aug 2020 22:39:00

**US3462076**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User entered 'mmHg'	System	10 Aug 2020 22:39:00

**US3462076**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03

US3462076

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03

US3462076

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:39:14

US3462076

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Sep 2020 16:57:29
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	10 Sep 2020 23:16:19
User entered '07 Aug 2020'	Danuel Hamlin (b) (4)	10 Aug 2020 22:39:14

US3462076

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:51:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '07 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:39:33

US3462076

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:51:48

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:39:33



US3462076

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:51:48

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:39:33

US3462076

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:51:48

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:39:33

US3462076

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:39:33

US3462076

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:51:48

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:39:33

US3462076

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:39:33

US3462076

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:51:48

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:39:33

US3462076

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:51:48

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:40:04

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Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:51:48

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '07 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:40:04



US3462076

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:51:48

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Urine (URINE)'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:40:04

US3462076

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:51:48

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Negative (NEGATIVE)'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:40:04

US3462076

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:51:48

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User closed query 'Per CDM, FSH sample recorded as not collected, however collection date/time are provided. Please reconcile.' (Site from DM).	(b) (4)	
Query 'Per CDM, FSH sample recorded as not collected, however collection date/time are provided. Please reconcile.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 07:06:39
User opened query 'Per CDM, FSH sample recorded as not collected, however collection date/time are provided. Please reconcile.' (Site from DM).	Savannah Peterson (b) (4)	05 Nov 2020 22:18:28
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	17 Sep 2020 16:24:39
	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:04

US3462076

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:51:48

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty; reason for change Data Entry Error	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:18:20
User entered '07 Aug 2020'	(b) (4)	
	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:04

US3462076

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:51:48

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty; reason for change Data Entry Error	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:18:20
User entered '10:25'	(b) (4)	
	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:04

**US3462076**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:51:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User entered empty.	System	05 Nov 2020 22:18:20
User entered '07 Aug 2020 10:25'	System	10 Aug 2020 22:40:04

US3462076

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:48

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:40:20

US3462076

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:48

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:40:20



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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:48

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:40:20

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:48

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'No (N)'	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:20

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:48

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:40:20

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:48

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'No (N)'	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:20

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:48

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'No (N)'	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:20

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:48

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Yes (Y)'	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:20

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:48

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:40:20

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:48

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'No (N)'	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:20



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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:48

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'No (N)'	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:20

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:48

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'No (N)'	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:20

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:40:20

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:48

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'I'	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:20

US3462076

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:48

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '0'	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:20

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:48

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '0'	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:20

US3462076

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:48

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:40:20

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:48

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '0'	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:20



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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:48

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '0'	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:20

US3462076

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:48

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:40:20

US3462076

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:51:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:40:20

US3462076

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:51:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:44:25

US3462076

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:51:48

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '07 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:44:25

US3462076

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:51:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Clinic (Clinic)'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:44:25

**US3462076**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:51:48**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'VISIT1'	System	10 Aug 2020 22:44:25

US3462076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '07 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 18:19:18



US3462076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:51:48

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 02:54:48
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:54:48
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 18:19:18
User entered '101997' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 18:19:18

US3462076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:51:48

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 18:19:18

US3462076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:51:48

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)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'No (N)'	Danuel Hamlin (b) (4)	10 Aug 2020 22:44:35

US3462076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:51:48

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)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'No (N)'	Danuel Hamlin (b) (4)	10 Aug 2020 22:44:35

US3462076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:51:48

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:44:35

US3462076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:51:48

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:44:35

US3462076

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:51:48

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:44:35

US3462076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:48

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 21:05:11
User entered '169.6' cm reason for change: Data Entry Error	Danuel Hamlin (b) (4)	10 Aug 2020 22:42:01
User entered empty.	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:36



US3462076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:48

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 21:05:11
User entered '76.3' kg reason for change: Data Entry Error	Danuel Hamlin (b) (4)	10 Aug 2020 22:42:01
User entered empty.	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:36

US3462076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:48

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 21:05:11
User entered '169.6' cm reason for change: Data Entry Error	Danuel Hamlin (b) (4)	10 Aug 2020 22:42:01
User entered empty.	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:36

US3462076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:48

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 21:05:11
User entered '76.3' kg reason for change: Data Entry Error	Danuel Hamlin (b) (4)	10 Aug 2020 22:42:01
User entered empty.	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:36

US3462076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User accepted default value 'Pre-Dose (PREDOSE)'	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:36

US3462076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Aug 2020 22:42:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	10 Aug 2020 22:42:01
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Aug 2020 22:40:36
User entered empty.	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:36

US3462076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '07 Aug 2020' reason for change: Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:42:01
User entered empty.	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:36

US3462076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '10:35' reason for change: Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:42:01
User entered empty.	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:36

**US3462076**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:51:48**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered '07 Aug 2020 10:35'	System	10 Aug 2020 22:42:01
User entered empty.	System	10 Aug 2020 22:40:36



US3462076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '98.4' F reason for change: Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:42:01
User entered empty.	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:36

US3462076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 21:05:11
User entered 'Oral (Oral)' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	10 Aug 2020 22:42:01
User entered empty.	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:36

US3462076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Tympanic' reason for change: Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 21:05:11
User entered empty.	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:36

US3462076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '75' reason for change: Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:42:01
User entered empty.	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:36

**US3462076**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:51:48**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'bpm'	System	10 Aug 2020 22:42:01
User entered empty.	System	10 Aug 2020 22:40:36

US3462076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '14' reason for change: Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:42:01
User entered empty.	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:36

US3462076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'breaths/min'	System	10 Aug 2020 22:42:01
User entered empty.	System	10 Aug 2020 22:40:36

US3462076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '104' reason for change: Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:42:01
User entered empty.	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:36



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'mmHg'	System	10 Aug 2020 22:42:01
User entered empty.	System	10 Aug 2020 22:40:36

US3462076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '70' reason for change: Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:42:01
User entered empty.	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:36

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:48

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'mmHg'	System	10 Aug 2020 22:42:01
User entered empty.	System	10 Aug 2020 22:40:36

US3462076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:48

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 21:05:11
User entered '169.6' cm reason for change: Data Entry Error	Danuel Hamlin (b) (4)	10 Aug 2020 22:42:01
User entered empty.	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:36

US3462076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:51:48

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 21:05:11
User entered '76.3' kg reason for change: Data Entry Error	Danuel Hamlin (b) (4)	10 Aug 2020 22:42:01
User entered empty.	Danuel Hamlin (b) (4)	10 Aug 2020 22:40:36

US3462076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User accepted default value 'Post-Dose (POSTDOSE)'	Danuel Hamlin (b) (4)	10 Aug 2020 22:43:08

US3462076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:43:08

US3462076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '07 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:43:08



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:26:49
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		10 Aug 2020 22:43:08
User entered '11:59'	Danuel Hamlin (b) (4)	10 Aug 2020 22:43:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered '07 Aug 2020 11:59'	System	10 Aug 2020 22:43:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '98.2' F	Danuel Hamlin (b) (4)	10 Aug 2020 22:43:08

US3462076

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 21:05:11
User entered 'Oral (Oral)'	Danuel Hamlin (b) (4)	10 Aug 2020 22:43:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Tympanic' reason for change: Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	02 Oct 2020 21:05:11
User entered empty.	Danuel Hamlin (b) (4)	10 Aug 2020 22:43:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '80'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:43:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'bpm'	System	10 Aug 2020 22:43:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '12'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:43:08



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'breaths/min'	System	10 Aug 2020 22:43:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '114'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:43:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'mmHg'	System	10 Aug 2020 22:43:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '78'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:43:08

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'mmHg'	System	10 Aug 2020 22:43:08

US3462076

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:43:23

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty.	Danuel Hamlin (b) (4)	10 Aug 2020 22:43:23

US3462076

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:51:48

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User closed query 'Per CDM: Per CCG page 40, if participant is screened and dosed on the same day, record pregnancy test as collected at Screening and not collected at Day 1. Please enter "NO" for 'Was the pregnancy test performed?' and 'Was FSH sample collected' and remove all the other data on this form. Thank you. ' (Site from DM).		15 Apr 2021 16:19:25
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:55:04
Query 'Per CDM: Per CCG page 40, if participant is screened and dosed on the same day, record pregnancy test as collected at Screening and not collected at Day 1. Please enter "NO" for 'Was the pregnancy test performed?' and 'Was FSH sample collected' and remove all the other data on this form. Thank you. ' answered with 'updated data' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:30:10
User entered 'No (N)' reason for change: Data Entry Error		06 Apr 2021 19:30:04
User opened query 'Per CDM: Per CCG page 40, if participant is screened and dosed on the same day, record pregnancy test as collected at Screening and not collected at Day 1. Please enter "NO" for 'Was the pregnancy test performed?' and 'Was FSH sample collected' and remove all the other data on this form. Thank you. ' (Site from DM).		06 Apr 2021 12:22:26
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 23:07:48
User entered 'Yes (Y)' reason for change: Data Entry Error		05 Apr 2021 23:07:48
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:43:34



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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:51:48

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:55:04
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:30:04
Signature has been broken.		05 Apr 2021 23:07:48
User entered '07 Aug 2020' reason for change: Data Entry Error		05 Apr 2021 23:07:48
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:43:34

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:51:48

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:55:04
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:30:04
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 23:08:09
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 23:08:09
User entered 'Urine (URINE)' reason for change: Data Entry Error		05 Apr 2021 23:08:09
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 23:07:48
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:43:34

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:51:48

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:55:04
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Apr 2021 19:30:04
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 23:08:09
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 23:08:09
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error		05 Apr 2021 23:08:09
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 23:07:48
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:43:34

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:51:48

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 22:55:04
User closed query 'Per CDM: Please provide a response to Was FSH sample collected?' (Site from DM).	(b) (4)	06 Apr 2021 12:18:57
Query 'Per CDM: Please provide a response to Was FSH sample collected?' answered with 'Data Updated' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 23:08:37
Signature has been broken.		05 Apr 2021 23:07:48
User entered 'No (N)' reason for change: Data Entry Error		05 Apr 2021 23:07:48
User opened query 'Per CDM: Please provide a response to Was FSH sample collected?' (Site from DM).		19 Mar 2021 20:07:46
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty.	(b) (4)	
	Danuel Hamlin (b) (4)	10 Aug 2020 22:43:34

US3462076

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:51:48

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty.	Danuel Hamlin (b) (4)	10 Aug 2020 22:43:34

**US3462076**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:51:48**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty.	Danuel Hamlin (b) (4)	10 Aug 2020 22:43:34

**US3462076**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:51:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:53:03
User entered empty.	System	10 Aug 2020 22:43:34

US3462076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	07 Aug 2020 18:33:46



US3462076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty.	Savannah Peterson (b) (4)	07 Aug 2020 18:33:46

US3462076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:48

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)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty.	Savannah Peterson (b) (4)	07 Aug 2020 18:33:46

US3462076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'MRNA-1273 OR PLACEBO'	System	07 Aug 2020 18:33:46

US3462076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '07 Aug 2020'	Savannah Peterson (b) (4)	07 Aug 2020 18:33:46

US3462076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:48

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '11:29'	Savannah Peterson (b) (4)	07 Aug 2020 18:33:46

US3462076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:48

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered '07 Aug 2020 11:29'	System	07 Aug 2020 18:33:46

US3462076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:48

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Left Arm (LEFT ARM)'	Savannah Peterson (b) (4)	07 Aug 2020 18:33:46

US3462076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:48

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'ONCE'	System	07 Aug 2020 18:33:46



US3462076

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:51:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'INTRAMUSCULAR'	System	07 Aug 2020 18:33:46

US3462076

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:43:59

US3462076

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '07 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:43:59

US3462076

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '11:10'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:43:59

US3462076

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered '07 Aug 2020 11:10'	System	10 Aug 2020 22:43:59

US3462076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:51:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 17Aug2020 is reported in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 10:50:50
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 17Aug2020 is reported in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' answered with 'added missing data' (Site from DM).		24 Feb 2021 17:53:33
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 17Aug2020 is reported in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).		24 Nov 2020 09:41:46
User entered '07 Aug 2020'	Danuel Hamlin (b) (4)	10 Aug 2020 22:44:11

US3462076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:51:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Danuel Hamlin (b) (4)	10 Aug 2020 22:44:11

US3462076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:51:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:44:11



US3462076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:51:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered '11:13'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:44:11

**US3462076**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:51:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered '07 Aug 2020 11:13'	System	10 Aug 2020 22:44:11

US3462076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:51:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Danuel Hamlin (b) (4)	10 Aug 2020 22:44:11

US3462076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:51:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:44:11

US3462076

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:51:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	10 Aug 2020 22:44:11

**US3462076**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:51:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered empty.	System	10 Aug 2020 22:44:11

US3462076

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:51:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	04 Sep 2020 18:54:40

**US3462076**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:51:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'I'	System	04 Sep 2020 18:54:40



US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T12:00:47', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '28149f1d-f0f5-4835-a978-6270163a2dee'	System	07 Aug 2020 19:01:10
User entered 'Yes (Y)'	System	07 Aug 2020 19:01:10

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T12:00:53', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '28149f1d-f0f5-4835-a978-6270163a2dee'	System	07 Aug 2020 19:01:10
User entered '98.2'	System	07 Aug 2020 19:01:10

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T12:01:01', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '28149f1d-f0f5-4835-a978-6270163a2dee'	System	07 Aug 2020 19:01:10
User entered 'No (N)'	System	07 Aug 2020 19:01:10

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T12:01:05', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '28149f1d-f0f5-4835-a978-6270163a2dee'	System	07 Aug 2020 19:01:10
User entered '07 Aug 2020 12:01'	System	07 Aug 2020 19:01:10

**US3462076**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '07 Aug 2020 11:49'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '07 Aug 2020 14:19'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 18:33:46



US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T15:22:01', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'defdf503-7ef2-4f50-a85e-a5fa72b4e990'	System	07 Aug 2020 22:22:19
User entered 'Yes (Y)'	System	07 Aug 2020 22:22:19

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T15:22:08', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'defdf503-7ef2-4f50-a85e-a5fa72b4e990'	System	07 Aug 2020 22:22:19
User entered '98.3'	System	07 Aug 2020 22:22:19

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T15:22:12', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'defdf503-7ef2-4f50-a85e-a5fa72b4e990'	System	07 Aug 2020 22:22:19
User entered 'No (N)'	System	07 Aug 2020 22:22:19

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T15:22:16', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'defdf503-7ef2-4f50-a85e-a5fa72b4e990'	System	07 Aug 2020 22:22:19
User entered '07 Aug 2020 15:22'	System	07 Aug 2020 22:22:19

**US3462076**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '07 Aug 2020 15:14'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 2'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:51:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-08T22:09:28', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'c83b3c3c-80a4-4d87-a439-5d4d4b2f27dd'	System	09 Aug 2020 05:10:27
User entered 'Yes (Y)'	System	09 Aug 2020 05:10:27



US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:51:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-08T22:10:10', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'c83b3c3c-80a4-4d87-a439-5d4d4b2f27dd'	System	09 Aug 2020 05:10:27
User entered '98.7'	System	09 Aug 2020 05:10:27

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-08T22:10:14', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'c83b3c3c-80a4-4d87-a439-5d4d4b2f27dd'	System	09 Aug 2020 05:10:27
User entered 'Yes (Y)'	System	09 Aug 2020 05:10:27

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	(b) (4)	13 Nov 2020 14:19:29
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Savannah Peterson (b) (4)	05 Nov 2020 21:46:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-08T22:10:20', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'c83b3c3c-80a4-4d87-a439-5d4d4b2f27dd'	(b) (4)	
User entered '1'	System	09 Aug 2020 05:10:27
	System	09 Aug 2020 05:10:27
	System	09 Aug 2020 05:10:27

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:51:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-08T22:10:20', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'c83b3c3c-80a4-4d87-a439-5d4d4b2f27dd'	System	09 Aug 2020 05:10:27
User entered '0'	System	09 Aug 2020 05:10:27

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:51:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-08T22:10:25', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'c83b3c3c-80a4-4d87-a439-5d4d4b2f27dd'	System	09 Aug 2020 05:10:27
User entered '08 Aug 2020 22:10'	System	09 Aug 2020 05:10:27

**US3462076**

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

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 18:33:46

**US3462076**

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

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 3'	System	07 Aug 2020 18:33:46



US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:51:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-09T20:08:39', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '30222d2c-d9e0-4648-b2aa-473079b24039'	System	10 Aug 2020 03:08:49
User entered 'Yes (Y)'	System	10 Aug 2020 03:08:49

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:51:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-09T20:08:42', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '30222d2c-d9e0-4648-b2aa-473079b24039'	System	10 Aug 2020 03:08:49
User entered '99.3'	System	10 Aug 2020 03:08:49

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-09T20:08:44', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '30222d2c-d9e0-4648-b2aa-473079b24039'	System	10 Aug 2020 03:08:49
User entered 'No (N)'	System	10 Aug 2020 03:08:49

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:51:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-09T20:08:47', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '30222d2c-d9e0-4648-b2aa-473079b24039'	System	10 Aug 2020 03:08:49
User entered '09 Aug 2020 20:08'	System	10 Aug 2020 03:08:49

**US3462076**

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

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

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:51:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 4'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:51:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-10T13:42:11', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '96b75262-8091-4208-9646-5791661a8665'	System	10 Aug 2020 20:42:26
User entered 'Yes (Y)'	System	10 Aug 2020 20:42:26



US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:51:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-10T13:42:14', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '96b75262-8091-4208-9646-5791661a8665'	System	10 Aug 2020 20:42:26
User entered '99.9'	System	10 Aug 2020 20:42:26

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-10T13:42:18', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '96b75262-8091-4208-9646-5791661a8665'	System	10 Aug 2020 20:42:26
User entered 'Yes (Y)'	System	10 Aug 2020 20:42:26

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 14:19:35
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-10T13:42:21', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '96b75262-8091-4208-9646-5791661a8665'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:46:54
User entered '1'	System	10 Aug 2020 20:42:26
	System	10 Aug 2020 20:42:26
	System	10 Aug 2020 20:42:26

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:51:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-10T13:42:21', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '96b75262-8091-4208-9646-5791661a8665'	System	10 Aug 2020 20:42:26
User entered '0'	System	10 Aug 2020 20:42:26

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:51:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-10T13:42:24', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '96b75262-8091-4208-9646-5791661a8665'	System	10 Aug 2020 20:42:26
User entered '10 Aug 2020 13:42'	System	10 Aug 2020 20:42:26

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:51:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 18:33:46

**US3462076**

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

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

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 5'	System	07 Aug 2020 18:33:46



US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:51:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-11T12:03:50', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '10fd3b08-e832-4b7e-8841-6be9fbd6f308'	System	11 Aug 2020 19:04:07
User entered 'Yes (Y)'	System	11 Aug 2020 19:04:07

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:51:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-11T12:03:53', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '10fd3b08-e832-4b7e-8841-6be9fbd6f308'	System	11 Aug 2020 19:04:07
User entered '99.7'	System	11 Aug 2020 19:04:07

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-11T12:03:59', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '10fd3b08-e832-4b7e-8841-6be9fbd6f308'	System	11 Aug 2020 19:04:07
User entered 'Yes (Y)'	System	11 Aug 2020 19:04:07

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 14:19:39
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Savannah Peterson (b) (4)	05 Nov 2020 21:47:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-11T12:04:01', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '10fd3b08-e832-4b7e-8841-6be9fbd6f308'	(b) (4)	
User entered '1'	System	11 Aug 2020 19:04:07
	System	11 Aug 2020 19:04:07
	System	11 Aug 2020 19:04:07

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:51:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-11T12:04:01', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '10fd3b08-e832-4b7e-8841-6be9fbd6f308'	System	11 Aug 2020 19:04:07
User entered '0'	System	11 Aug 2020 19:04:07

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:51:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-11T12:04:03', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '10fd3b08-e832-4b7e-8841-6be9fbd6f308'	System	11 Aug 2020 19:04:07
User entered '11 Aug 2020 12:04'	System	11 Aug 2020 19:04:07

**US3462076**

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

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:51:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 18:33:46



US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 6'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:51:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-12T17:03:00', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '30c3d575-9c6c-419b-bab2-fae553a99396'	System	13 Aug 2020 00:03:34
User entered 'Yes (Y)'	System	13 Aug 2020 00:03:34

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:51:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-12T17:03:24', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '30c3d575-9c6c-419b-bab2-fae553a99396'	System	13 Aug 2020 00:03:34
User entered '99.1'	System	13 Aug 2020 00:03:34

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-12T17:03:27', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '30c3d575-9c6c-419b-bab2-fae553a99396'	System	13 Aug 2020 00:03:34
User entered 'No (N)'	System	13 Aug 2020 00:03:34

**US3462076**

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

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-12T17:03:29', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '30c3d575-9c6c-419b-bab2-fae553a99396'	System	13 Aug 2020 00:03:34
User entered '12 Aug 2020 17:03'	System	13 Aug 2020 00:03:34

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:51:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 18:33:46

**US3462076**

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

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 7'	System	07 Aug 2020 18:33:46



US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:51:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-13T12:03:14', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '9e6f743c-d63d-4d7f-aa88-792c3c355b3f'	System	13 Aug 2020 19:03:34
User entered 'Yes (Y)'	System	13 Aug 2020 19:03:34

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:51:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-13T12:03:29', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '9e6f743c-d63d-4d7f-aa88-792c3c355b3f'	System	13 Aug 2020 19:03:34
User entered '98.4'	System	13 Aug 2020 19:03:34

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-13T12:03:31', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '9e6f743c-d63d-4d7f-aa88-792c3c355b3f'	System	13 Aug 2020 19:03:34
User entered 'No (N)'	System	13 Aug 2020 19:03:34

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:51:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-13T12:03:33', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '9e6f743c-d63d-4d7f-aa88-792c3c355b3f'	System	13 Aug 2020 19:03:34
User entered '13 Aug 2020 12:03'	System	13 Aug 2020 19:03:34

US3462076

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:51:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 18:33:46

**US3462076**

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

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T12:01:33', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5305b909-24ee-4b54-b8a6-a358fd9c28e9'	System	07 Aug 2020 19:01:58
User entered 'None (1)'	System	07 Aug 2020 19:01:58



US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T12:01:36', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5305b909-24ee-4b54-b8a6-a358fd9c28e9'	System	07 Aug 2020 19:01:58
User entered 'No (N)'	System	07 Aug 2020 19:01:58

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T12:01:40', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5305b909-24ee-4b54-b8a6-a358fd9c28e9'	System	07 Aug 2020 19:01:58
User entered 'No (N)'	System	07 Aug 2020 19:01:58

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T12:01:52', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5305b909-24ee-4b54-b8a6-a358fd9c28e9'	System	07 Aug 2020 19:01:58
User entered 'None (1)'	System	07 Aug 2020 19:01:58

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T12:01:55', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5305b909-24ee-4b54-b8a6-a358fd9c28e9'	System	07 Aug 2020 19:01:58
User entered '07 Aug 2020 12:01'	System	07 Aug 2020 19:01:58

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '07 Aug 2020 11:49'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '07 Aug 2020 14:19'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T15:22:36', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'ed62e1c1-1af0-404d-8eb8-cd8b3d191eb5'	System	07 Aug 2020 22:24:14
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'		07 Aug 2020 22:24:14



US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T15:22:44', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'ed62e1c1-1af0-404d-8eb8-cd8b3d191eb5'	System	07 Aug 2020 22:24:14
User entered 'No (N)'	System	07 Aug 2020 22:24:14

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T15:22:52', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'ed62e1c1-1af0-404d-8eb8-cd8b3d191eb5'	System	07 Aug 2020 22:24:14
User entered 'No (N)'	System	07 Aug 2020 22:24:14

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T15:24:08', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'ed62e1c1-1af0-404d-8eb8-cd8b3d191eb5'	System	07 Aug 2020 22:24:14
User entered 'None (1)'	System	07 Aug 2020 22:24:14

**US3462076**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T15:24:12', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'ed62e1c1-1af0-404d-8eb8-cd8b3d191eb5'	System	07 Aug 2020 22:24:14
User entered '07 Aug 2020 15:24'	System	07 Aug 2020 22:24:14

**US3462076**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '07 Aug 2020 15:14'	System	07 Aug 2020 18:33:46

**US3462076**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 2'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-08T22:10:40', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'a9b10457-a336-40dd-8fd2-06c3eb0edf53'	System	09 Aug 2020 05:11:34
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	09 Aug 2020 05:11:34



US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:51:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-08T22:10:43', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'a9b10457-a336-40dd-8fd2-06c3eb0edf53'	System	09 Aug 2020 05:11:34
User entered 'No (N)'	System	09 Aug 2020 05:11:34

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-08T22:10:48', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'a9b10457-a336-40dd-8fd2-06c3eb0edf53'	System	09 Aug 2020 05:11:34
User entered 'No (N)'	System	09 Aug 2020 05:11:34

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-08T22:11:29', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'a9b10457-a336-40dd-8fd2-06c3eb0edf53'	System	09 Aug 2020 05:11:34
User entered 'Does not interfere with activity (2)'	System	09 Aug 2020 05:11:34

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:51:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-08T22:11:32', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'a9b10457-a336-40dd-8fd2-06c3eb0edf53'	System	09 Aug 2020 05:11:34
User entered '08 Aug 2020 22:11'	System	09 Aug 2020 05:11:34

**US3462076**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:51:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 3'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-09T20:08:50', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'ddd3b8c9-82f3-4ca6-a135-381e21a9ffdd'	System	10 Aug 2020 03:09:05
User entered 'None (1)'	System	10 Aug 2020 03:09:05



US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-09T20:08:52', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'ddd3b8c9-82f3-4ca6-a135-381e21a9ffdd'	System	10 Aug 2020 03:09:05
User entered 'No (N)'	System	10 Aug 2020 03:09:05

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-09T20:08:55', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'ddd3b8c9-82f3-4ca6-a135-381e21a9ffdd'	System	10 Aug 2020 03:09:05
User entered 'No (N)'	System	10 Aug 2020 03:09:05

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-09T20:09:01', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'ddd3b8c9-82f3-4ca6-a135-381e21a9ffdd'	System	10 Aug 2020 03:09:05
User entered 'None (1)'	System	10 Aug 2020 03:09:05

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:51:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-09T20:09:04', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'ddd3b8c9-82f3-4ca6-a135-381e21a9ffdd'	System	10 Aug 2020 03:09:05
User entered '09 Aug 2020 20:09'	System	10 Aug 2020 03:09:05

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:51:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 18:33:46

**US3462076**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 4'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-10T13:42:27', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'c8d1e729-8c9a-4405-8a99-a4c87a01e155'	System	10 Aug 2020 20:42:40
User entered 'None (1)'	System	10 Aug 2020 20:42:40



US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-10T13:42:29', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'c8d1e729-8c9a-4405-8a99-a4c87a01e155'	System	10 Aug 2020 20:42:40
User entered 'No (N)'	System	10 Aug 2020 20:42:40

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-10T13:42:31', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'c8d1e729-8c9a-4405-8a99-a4c87a01e155'	System	10 Aug 2020 20:42:40
User entered 'No (N)'	System	10 Aug 2020 20:42:40

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-10T13:42:34', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'c8d1e729-8c9a-4405-8a99-a4c87a01e155'	System	10 Aug 2020 20:42:40
User entered 'None (1)'	System	10 Aug 2020 20:42:40

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:51:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-10T13:42:36', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'c8d1e729-8c9a-4405-8a99-a4c87a01e155'	System	10 Aug 2020 20:42:40
User entered '10 Aug 2020 13:42'	System	10 Aug 2020 20:42:40

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:51:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:51:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 5'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-11T12:04:21', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '6be6f29b-73b9-4184-a57c-0d571d19bd2d'	System	11 Aug 2020 19:04:40
User entered 'None (1)'	System	11 Aug 2020 19:04:40



US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-11T12:04:23', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '6be6f29b-73b9-4184-a57c-0d571d19bd2d'	System	11 Aug 2020 19:04:40
User entered 'No (N)'	System	11 Aug 2020 19:04:40

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-11T12:04:25', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '6be6f29b-73b9-4184-a57c-0d571d19bd2d'	System	11 Aug 2020 19:04:40
User entered 'No (N)'	System	11 Aug 2020 19:04:40

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-11T12:04:34', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '6be6f29b-73b9-4184-a57c-0d571d19bd2d'	System	11 Aug 2020 19:04:40
User entered 'Does not interfere with activity (2)'	System	11 Aug 2020 19:04:40

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:51:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-11T12:04:37', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '6be6f29b-73b9-4184-a57c-0d571d19bd2d'	System	11 Aug 2020 19:04:40
User entered '11 Aug 2020 12:04'	System	11 Aug 2020 19:04:40

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:51:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:51:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 6'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-12T17:03:33', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'cffe0815-7b28-4246-9b3b-7e2a36c4169f'	System	13 Aug 2020 00:03:50
User entered 'None (1)'	System	13 Aug 2020 00:03:50



US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-12T17:03:35', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'cffe0815-7b28-4246-9b3b-7e2a36c4169f'	System	13 Aug 2020 00:03:50
User entered 'No (N)'	System	13 Aug 2020 00:03:50

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-12T17:03:36', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'cffe0815-7b28-4246-9b3b-7e2a36c4169f'	System	13 Aug 2020 00:03:50
User entered 'No (N)'	System	13 Aug 2020 00:03:50

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-12T17:03:43', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'cffe0815-7b28-4246-9b3b-7e2a36c4169f'	System	13 Aug 2020 00:03:50
User entered 'None (1)'	System	13 Aug 2020 00:03:50

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:51:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-12T17:03:45', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'cffe0815-7b28-4246-9b3b-7e2a36c4169f'	System	13 Aug 2020 00:03:50
User entered '12 Aug 2020 17:03'	System	13 Aug 2020 00:03:50

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:51:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 18:33:46

**US3462076**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 7'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-13T12:03:35', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'a9881a6e-cc75-4dfb-81c8-559dbf4def1d'	System	13 Aug 2020 19:03:43
User entered 'None (1)'	System	13 Aug 2020 19:03:43



US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-13T12:03:37', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'a9881a6e-cc75-4dfb-81c8-559dbf4def1d'	System	13 Aug 2020 19:03:43
User entered 'No (N)'	System	13 Aug 2020 19:03:43

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-13T12:03:38', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'a9881a6e-cc75-4dfb-81c8-559dbf4def1d'	System	13 Aug 2020 19:03:43
User entered 'No (N)'	System	13 Aug 2020 19:03:43

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-13T12:03:39', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'a9881a6e-cc75-4dfb-81c8-559dbf4def1d'	System	13 Aug 2020 19:03:43
User entered 'None (1)'	System	13 Aug 2020 19:03:43

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:51:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-13T12:03:41', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'a9881a6e-cc75-4dfb-81c8-559dbf4def1d'	System	13 Aug 2020 19:03:43
User entered '13 Aug 2020 12:03'	System	13 Aug 2020 19:03:43

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:51:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:51:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T12:02:22', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'd841123e-58a7-48aa-8559-6384b787e32b'	System	07 Aug 2020 19:02:47
User entered 'No interference with activity (1)'	System	07 Aug 2020 19:02:47



US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T12:02:27', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'd841123e-58a7-48aa-8559-6384b787e32b'	System	07 Aug 2020 19:02:47
User entered 'None (0)'	System	07 Aug 2020 19:02:47

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T12:02:31', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'd841123e-58a7-48aa-8559-6384b787e32b'	System	07 Aug 2020 19:02:47
User entered 'None (0)'	System	07 Aug 2020 19:02:47

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T12:02:34', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'd841123e-58a7-48aa-8559-6384b787e32b'	System	07 Aug 2020 19:02:47
User entered 'None (0)'	System	07 Aug 2020 19:02:47

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T12:02:36', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'd841123e-58a7-48aa-8559-6384b787e32b'	System	07 Aug 2020 19:02:47
User entered 'None (0)'	System	07 Aug 2020 19:02:47

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T12:02:39', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'd841123e-58a7-48aa-8559-6384b787e32b'	System	07 Aug 2020 19:02:47
User entered 'No interference with activity (1)'	System	07 Aug 2020 19:02:47

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T12:02:43', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'd841123e-58a7-48aa-8559-6384b787e32b'	System	07 Aug 2020 19:02:47
User entered 'No (N)'	System	07 Aug 2020 19:02:47

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T12:02:45', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'd841123e-58a7-48aa-8559-6384b787e32b'	System	07 Aug 2020 19:02:47
User entered '07 Aug 2020 12:02'	System	07 Aug 2020 19:02:47

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '07 Aug 2020 11:49'	System	07 Aug 2020 18:33:46



**US3462076**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '07 Aug 2020 14:19'	System	07 Aug 2020 18:33:46

**US3462076**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T15:24:18', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '733fe85d-0846-453c-a2b2-8d4bbf042277'	System	07 Aug 2020 22:26:18
User entered 'No interference with activity (1)'	System	07 Aug 2020 22:26:18

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T15:24:22', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '733fe85d-0846-453c-a2b2-8d4bbf042277'	System	07 Aug 2020 22:26:18
User entered 'Significant; prevents daily activity (3)'	System	07 Aug 2020 22:26:18

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T15:24:26', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '733fe85d-0846-453c-a2b2-8d4bbf042277'	System	07 Aug 2020 22:26:18
User entered 'No interference with activity (1)'	System	07 Aug 2020 22:26:18

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T15:25:32', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '733fe85d-0846-453c-a2b2-8d4bbf042277'	System	07 Aug 2020 22:26:18
User entered 'No interference with activity (1)'	System	07 Aug 2020 22:26:18

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T15:25:36', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '733fe85d-0846-453c-a2b2-8d4bbf042277'	System	07 Aug 2020 22:26:18
User entered 'None (0)'	System	07 Aug 2020 22:26:18

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T15:25:56', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '733fe85d-0846-453c-a2b2-8d4bbf042277'	System	07 Aug 2020 22:26:18
User entered 'No interference with activity (1)'	System	07 Aug 2020 22:26:18



US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T15:26:07', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '733fe85d-0846-453c-a2b2-8d4bbf042277'	System	07 Aug 2020 22:26:18
User entered 'No (N)'	System	07 Aug 2020 22:26:18

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-07T15:26:17', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '733fe85d-0846-453c-a2b2-8d4bbf042277'	System	07 Aug 2020 22:26:18
User entered '07 Aug 2020 15:26'	System	07 Aug 2020 22:26:18

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '07 Aug 2020 15:14'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 2'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:51:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-08T22:11:37', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'f69ee9b2-a666-4aa1-b7d3-bb6815cb8c1d'	System	09 Aug 2020 05:12:16
User entered 'No interference with activity (1)'	System	09 Aug 2020 05:12:16

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:51:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-08T22:11:41', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'f69ee9b2-a666-4aa1-b7d3-bb6815cb8c1d'	System	09 Aug 2020 05:12:16
User entered 'Some interference with activity (2)'	System	09 Aug 2020 05:12:16

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:51:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-08T22:11:53', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'f69ee9b2-a666-4aa1-b7d3-bb6815cb8c1d'	System	09 Aug 2020 05:12:16
User entered 'Some interference with activity (2)'	System	09 Aug 2020 05:12:16



US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:51:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-08T22:11:50', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'f69ee9b2-a666-4aa1-b7d3-bb6815cb8c1d'	System	09 Aug 2020 05:12:16
User entered 'No interference with activity (1)'	System	09 Aug 2020 05:12:16

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:51:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-08T22:12:04', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'f69ee9b2-a666-4aa1-b7d3-bb6815cb8c1d'	System	09 Aug 2020 05:12:16
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	09 Aug 2020 05:12:16

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:51:48

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-08T22:12:07', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'f69ee9b2-a666-4aa1-b7d3-bb6815cb8c1d'	System	09 Aug 2020 05:12:16
User entered 'None (0)'	System	09 Aug 2020 05:12:16

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-08T22:12:11', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'f69ee9b2-a666-4aa1-b7d3-bb6815cb8c1d'	System	09 Aug 2020 05:12:16
User entered 'No (N)'	System	09 Aug 2020 05:12:16

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:51:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-08T22:12:13', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'f69ee9b2-a666-4aa1-b7d3-bb6815cb8c1d'	System	09 Aug 2020 05:12:16
User entered '08 Aug 2020 22:12'	System	09 Aug 2020 05:12:16

**US3462076**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 18:33:46

**US3462076**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 3'	System	07 Aug 2020 18:33:46



US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:51:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-09T20:09:08', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'f9299308-e915-4dbe-84b4-9c67d2f85147'	System	10 Aug 2020 03:09:37
User entered 'None (0)'	System	10 Aug 2020 03:09:37

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:51:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-09T20:09:12', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'f9299308-e915-4dbe-84b4-9c67d2f85147'	System	10 Aug 2020 03:09:37
User entered 'Some interference with activity (2)'	System	10 Aug 2020 03:09:37

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:51:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-09T20:09:17', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'f9299308-e915-4dbe-84b4-9c67d2f85147'	System	10 Aug 2020 03:09:37
User entered 'No interference with activity (1)'	System	10 Aug 2020 03:09:37

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:51:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-09T20:09:20', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'f9299308-e915-4dbe-84b4-9c67d2f85147'	System	10 Aug 2020 03:09:37
User entered 'No interference with activity (1)'	System	10 Aug 2020 03:09:37

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:51:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-09T20:09:24', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'f9299308-e915-4dbe-84b4-9c67d2f85147'	System	10 Aug 2020 03:09:37
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	10 Aug 2020 03:09:37

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:51:48

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-09T20:09:29', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'f9299308-e915-4dbe-84b4-9c67d2f85147'	System	10 Aug 2020 03:09:37
User entered 'No interference with activity (1)'	System	10 Aug 2020 03:09:37

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-09T20:09:32', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'f9299308-e915-4dbe-84b4-9c67d2f85147'	System	10 Aug 2020 03:09:37
User entered 'No (N)'	System	10 Aug 2020 03:09:37

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:51:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-09T20:09:34', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'f9299308-e915-4dbe-84b4-9c67d2f85147'	System	10 Aug 2020 03:09:37
User entered '09 Aug 2020 20:09'	System	10 Aug 2020 03:09:37



**US3462076**

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

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

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 18:33:46

**US3462076**

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

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

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 4'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:51:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-10T13:42:41', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '46da49bc-f56c-490f-af5e-c5f4c61c8f15'	System	10 Aug 2020 20:43:04
User entered 'None (0)'	System	10 Aug 2020 20:43:04

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:51:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-10T13:42:46', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '46da49bc-f56c-490f-af5e-c5f4c61c8f15'	System	10 Aug 2020 20:43:04
User entered 'Significant; prevents daily activity (3)'	System	10 Aug 2020 20:43:04

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:51:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-10T13:42:49', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '46da49bc-f56c-490f-af5e-c5f4c61c8f15'	System	10 Aug 2020 20:43:04
User entered 'Some interference with activity (2)'	System	10 Aug 2020 20:43:04

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:51:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-10T13:42:52', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '46da49bc-f56c-490f-af5e-c5f4c61c8f15'	System	10 Aug 2020 20:43:04
User entered 'Some interference with activity (2)'	System	10 Aug 2020 20:43:04

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:51:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-10T13:42:54', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '46da49bc-f56c-490f-af5e-c5f4c61c8f15'	System	10 Aug 2020 20:43:04
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	10 Aug 2020 20:43:04



US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:51:48

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-10T13:42:58', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '46da49bc-f56c-490f-af5e-c5f4c61c8f15'	System	10 Aug 2020 20:43:04
User entered 'No interference with activity (1)'	System	10 Aug 2020 20:43:04

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-10T13:43:01', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '46da49bc-f56c-490f-af5e-c5f4c61c8f15'	System	10 Aug 2020 20:43:04
User entered 'No (N)'	System	10 Aug 2020 20:43:04

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:51:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-10T13:43:02', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '46da49bc-f56c-490f-af5e-c5f4c61c8f15'	System	10 Aug 2020 20:43:04
User entered '10 Aug 2020 13:43'	System	10 Aug 2020 20:43:04

**US3462076**

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

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

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 18:33:46

**US3462076**

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

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

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 18:33:46

**US3462076**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 5'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:51:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-11T12:04:47', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '2bb2d70a-2130-4213-a79c-8702f963b948'	System	11 Aug 2020 19:05:11
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	11 Aug 2020 19:05:11

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:51:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-11T12:04:51', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '2bb2d70a-2130-4213-a79c-8702f963b948'	System	11 Aug 2020 19:05:11
User entered 'Some interference with activity (2)'	System	11 Aug 2020 19:05:11



US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:51:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-11T12:04:53', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '2bb2d70a-2130-4213-a79c-8702f963b948'	System	11 Aug 2020 19:05:11
User entered 'Some interference with activity (2)'	System	11 Aug 2020 19:05:11

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:51:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-11T12:04:54', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '2bb2d70a-2130-4213-a79c-8702f963b948'	System	11 Aug 2020 19:05:11
User entered 'Some interference with activity (2)'	System	11 Aug 2020 19:05:11

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:51:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-11T12:05:00', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '2bb2d70a-2130-4213-a79c-8702f963b948'	System	11 Aug 2020 19:05:11
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	11 Aug 2020 19:05:11

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:51:48

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-11T12:05:05', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '2bb2d70a-2130-4213-a79c-8702f963b948'	System	11 Aug 2020 19:05:11
User entered 'No interference with activity (1)'	System	11 Aug 2020 19:05:11

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-11T12:05:07', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '2bb2d70a-2130-4213-a79c-8702f963b948'	System	11 Aug 2020 19:05:11
User entered 'No (N)'	System	11 Aug 2020 19:05:11

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:51:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-11T12:05:09', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '2bb2d70a-2130-4213-a79c-8702f963b948'	System	11 Aug 2020 19:05:11
User entered '11 Aug 2020 12:05'	System	11 Aug 2020 19:05:11

**US3462076**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 18:33:46

**US3462076**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 18:33:46



US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 6'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:51:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-12T17:04:23', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '94f414a5-4f26-4b5d-af48-4adda08962c2'	System	13 Aug 2020 00:04:44
User entered 'None (0)'	System	13 Aug 2020 00:04:44

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:51:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-12T17:04:30', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '94f414a5-4f26-4b5d-af48-4adda08962c2'	System	13 Aug 2020 00:04:44
User entered 'No interference with activity (1)'	System	13 Aug 2020 00:04:44

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:51:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-12T17:04:32', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '94f414a5-4f26-4b5d-af48-4adda08962c2'	System	13 Aug 2020 00:04:44
User entered 'None (0)'	System	13 Aug 2020 00:04:44

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:51:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-12T17:04:34', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '94f414a5-4f26-4b5d-af48-4adda08962c2'	System	13 Aug 2020 00:04:44
User entered 'None (0)'	System	13 Aug 2020 00:04:44

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:51:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-12T17:04:36', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '94f414a5-4f26-4b5d-af48-4adda08962c2'	System	13 Aug 2020 00:04:44
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	13 Aug 2020 00:04:44

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:51:48

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-12T17:04:38', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '94f414a5-4f26-4b5d-af48-4adda08962c2'	System	13 Aug 2020 00:04:44
User entered 'None (0)'	System	13 Aug 2020 00:04:44

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-12T17:04:40', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '94f414a5-4f26-4b5d-af48-4adda08962c2'	System	13 Aug 2020 00:04:44
User entered 'No (N)'	System	13 Aug 2020 00:04:44



US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:51:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-12T17:04:42', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '94f414a5-4f26-4b5d-af48-4adda08962c2'	System	13 Aug 2020 00:04:44
User entered '12 Aug 2020 17:04'	System	13 Aug 2020 00:04:44

**US3462076**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 18:33:46

**US3462076**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 18:33:46

**US3462076**

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

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 7'	System	07 Aug 2020 18:33:46

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:51:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-13T12:03:44', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '87c50403-a3b5-4c9f-ab99-31082357decc'	System	13 Aug 2020 19:03:56
User entered 'None (0)'	System	13 Aug 2020 19:03:56

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:51:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-13T12:03:45', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '87c50403-a3b5-4c9f-ab99-31082357decc'	System	13 Aug 2020 19:03:56
User entered 'None (0)'	System	13 Aug 2020 19:03:56

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:51:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-13T12:03:47', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '87c50403-a3b5-4c9f-ab99-31082357decc'	System	13 Aug 2020 19:03:56
User entered 'None (0)'	System	13 Aug 2020 19:03:56

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:51:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-13T12:03:48', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '87c50403-a3b5-4c9f-ab99-31082357decc'	System	13 Aug 2020 19:03:56
User entered 'None (0)'	System	13 Aug 2020 19:03:56



US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:51:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-13T12:03:49', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '87c50403-a3b5-4c9f-ab99-31082357decc'	System	13 Aug 2020 19:03:56
User entered 'None (0)'	System	13 Aug 2020 19:03:56

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:51:48

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-13T12:03:51', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '87c50403-a3b5-4c9f-ab99-31082357decc'	System	13 Aug 2020 19:03:56
User entered 'None (0)'	System	13 Aug 2020 19:03:56

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-13T12:03:52', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '87c50403-a3b5-4c9f-ab99-31082357decc'	System	13 Aug 2020 19:03:56
User entered 'No (N)'	System	13 Aug 2020 19:03:56

US3462076

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:51:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-13T12:03:54', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '87c50403-a3b5-4c9f-ab99-31082357decc'	System	13 Aug 2020 19:03:56
User entered '13 Aug 2020 12:03'	System	13 Aug 2020 19:03:56

**US3462076**

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

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 18:33:46

**US3462076**

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

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 18:33:46

**US3462076**

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

**Form: Medical Attention\_Day(8)**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	13 Aug 2020 00:04:44
User entered 'Day 8'	System	13 Aug 2020 00:04:44

US3462076

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-14T12:08:02', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'a848ed08-09fe-4ae6-be98-6743f1aa5df2'	System	14 Aug 2020 19:08:31
User entered 'No (N)'	System	14 Aug 2020 19:08:31



US3462076

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:51:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-08-14T12:08:05', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'a848ed08-09fe-4ae6-be98-6743f1aa5df2'	System	14 Aug 2020 19:08:31
User entered '14 Aug 2020 12:08'	System	14 Aug 2020 19:08:31

**US3462076**

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

**Form: Medical Attention\_Day(8)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 00:04:44

**US3462076**

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

**Form: Medical Attention\_Day(8)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 00:04:44

**US3462076**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:51:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	04 Sep 2020 18:56:00

US3462076

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User closed query 'Per GCL Lab Reconciliation Requery: Saliva: Per CCG V2.0, please create an illness visit using Add event option. Then update the SALIVA Collection form with the information for the Saliva Sample dated 21AUG2020 which is reported under Illness Visits in PPD Central lab. Else clarify, thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 08:53:58
Query 'Per GCL Lab Reconciliation Requery: Saliva: Per CCG V2.0, please create an illness visit using Add event option. Then update the SALIVA Collection form with the information for the Saliva Sample dated 21AUG2020 which is reported under Illness Visits in PPD Central lab. Else clarify, thank you' answered with 'added missing data' (Site from DM).		24 Feb 2021 17:53:08
User closed query 'Per GCL Lab Recon: GCL has a swab dated 17AUG2020, but this data is not present in the CRF. Please clarify or reconcile ' (Site from DM).		24 Nov 2020 09:47:55
User opened query 'Per GCL Lab Reconciliation Requery: Saliva: Per CCG V2.0, please create an illness visit using Add event option. Then update the SALIVA Collection form with the information for the Saliva Sample dated 21AUG2020 which is reported under Illness Visits in PPD Central lab. Else clarify, thank you' (Site from DM).		11 Nov 2020 12:28:47
User closed query 'Per GCL Lab Recon: GCL has Saliva Day 5, dated 21AUG2020; however there is no Saliva Log completed. Please reconcile or clarify' (Site from DM).		11 Nov 2020 12:28:47
Query 'Per GCL Lab Recon: GCL has Saliva Day 5, dated 21AUG2020; however there is no Saliva Log completed. Please reconcile or clarify' answered with 'updated' (Site from DM).	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:17:38
Query 'Per GCL Lab Recon: GCL has a swab dated 17AUG2020, but this data is not present in the CRF. Please clarify or reconcile ' answered with 'updated' (Site from DM).	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:17:32

US3462076

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:48

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Recon: GCL has Saliva Day 5, dated 21AUG2020; however there is no Saliva Log completed. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 18:54:46
User opened query 'Per GCL Lab Recon: GCL has a swab dated 17AUG2020, but this data is not present in the CRF. Please clarify or reconcile ' (Site from DM).		26 Oct 2020 17:44:22
User entered '14 Aug 2020'	Savannah Peterson (b) (4) (b) (4)	04 Sep 2020 18:56:00

US3462076

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Savannah Peterson (b) (4)	04 Sep 2020 18:56:00

US3462076

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:48

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered empty.	Savannah Peterson (b) (4)	04 Sep 2020 18:56:00



US3462076

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	04 Sep 2020 18:56:05

**US3462076**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:51:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered '1'	System	04 Sep 2020 18:56:05

**US3462076**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:51:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'No (N)'	Savannah Peterson (b) (4)	04 Sep 2020 18:56:51

US3462076

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty.	Savannah Peterson (b) (4)	04 Sep 2020 18:56:51

US3462076

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty.	Savannah Peterson (b) (4)	04 Sep 2020 18:56:51

US3462076

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:48

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'patient contacted via illness visit contact phone call by PI'	Savannah Peterson (b) (4)	04 Sep 2020 18:56:51

US3462076

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	04 Sep 2020 18:56:56

**US3462076**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:51:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'I'	System	04 Sep 2020 18:56:56



**US3462076**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:51:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	04 Sep 2020 18:57:14

US3462076

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '28 Aug 2020'	Savannah Peterson (b) (4)	04 Sep 2020 18:57:14

US3462076

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Contact Made (CONTACT MADE)'	Savannah Peterson (b) (4)	04 Sep 2020 18:57:14

US3462076

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:48

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty.	Savannah Peterson (b) (4)	04 Sep 2020 18:57:14

US3462076

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	04 Sep 2020 18:57:21

**US3462076**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:51:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'I'	System	04 Sep 2020 18:57:21

US3462076

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 23:16:19

US3462076

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:48

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 9OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 09:55:59
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 9OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'updated' (Site from DM).	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:18:59
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 9OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 06:56:33
User entered '04 Sep 2020'		10 Sep 2020 23:16:19



US3462076

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:16:19

**US3462076**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:51:48**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'VISIT2'	System	10 Sep 2020 23:16:19

**US3462076**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:51:48**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User accepted default value 'Pre-Dose (PREDOSE)'		10 Sep 2020 23:17:34

US3462076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 23:17:34

US3462076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered '04 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 23:17:34

US3462076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered '10:40'	(b) (4), (b) (6)	10 Sep 2020 23:17:34

US3462076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered '04 Sep 2020 10:40'	System	10 Sep 2020 23:17:34

US3462076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered '98.2' F	(b) (4), (b) (6)	10 Sep 2020 23:17:34



US3462076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered 'Other (Other)'	(b) (4), (b) (6)	10 Sep 2020 23:17:34

US3462076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered 'TYMPANIC'	(b) (4), (b) (6)	10 Sep 2020 23:17:34

US3462076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered '87'	(b) (4), (b) (6)	10 Sep 2020 23:17:34

**US3462076**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:51:48**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'bpm'	System	10 Sep 2020 23:17:34

US3462076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered '14'	(b) (4), (b) (6)	10 Sep 2020 23:17:34

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'breaths/min'	System	10 Sep 2020 23:17:34

US3462076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered '112'	(b) (4), (b) (6)	10 Sep 2020 23:17:34

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'mmHg'	System	10 Sep 2020 23:17:34



US3462076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered '70'	(b) (4), (b) (6)	10 Sep 2020 23:17:34

US3462076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:51:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'mmHg'	System	10 Sep 2020 23:17:34

US3462076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User accepted default value 'Post-Dose (POSTDOSE)'		10 Sep 2020 23:17:34

US3462076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 23:17:34

US3462076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered '04 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:17:34

US3462076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered '12:16'	(b) (4), (b) (6)	10 Sep 2020 23:17:34

US3462076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered '04 Sep 2020 12:16'	System	10 Sep 2020 23:17:34

US3462076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered '98.6' F	(b) (4), (b) (6)	10 Sep 2020 23:17:34



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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered 'Other (Other)'	(b) (4), (b) (6)	10 Sep 2020 23:17:34

US3462076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered 'TYMPANIC'	(b) (4), (b) (6)	10 Sep 2020 23:17:34

US3462076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered '71'	(b) (4), (b) (6)	10 Sep 2020 23:17:34

US3462076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'bpm'	System	10 Sep 2020 23:17:34

US3462076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered '14'	(b) (4), (b) (6)	10 Sep 2020 23:17:34

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'breaths/min'	System	10 Sep 2020 23:17:34

US3462076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered '106'	(b) (4), (b) (6)	10 Sep 2020 23:17:34

US3462076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'mmHg'	System	10 Sep 2020 23:17:34



US3462076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered '62'	(b) (4), (b) (6)	10 Sep 2020 23:17:34

US3462076

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:51:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'mmHg'	System	10 Sep 2020 23:17:34

US3462076

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:17:44

US3462076

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 23:17:44

US3462076

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:51:48

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:18:17

US3462076

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:51:48

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered '04 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 23:18:17

US3462076

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:51:48

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:18:17

US3462076

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:51:48

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:18:17



US3462076

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:51:48

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 23:18:17

**US3462076**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:51:48**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 23:18:17

US3462076

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:51:48

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 23:18:17

**US3462076**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:51:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered empty.	System	10 Sep 2020 23:18:17

US3462076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User closed query 'Per CDM: Please complete all appropriate pages for this visit.' (Site from DM).	(b) (4)	11 Sep 2020 16:56:16
Query 'Per CDM: Please complete all appropriate pages for this visit.' answered with 'CONFIRMED' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 23:19:22
User opened query 'Per CDM: Please complete all appropriate pages for this visit.' (Site from DM).		09 Sep 2020 13:53:02
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	04 Sep 2020 18:57:47
	(b) (4)	

US3462076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:48

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered empty.	Savannah Peterson (b) (4)	04 Sep 2020 18:57:47

US3462076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:48

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)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered empty.	Savannah Peterson (b) (4)	04 Sep 2020 18:57:47

US3462076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 18:57:47



US3462076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered '04 Sep 2020'	Savannah Peterson (b) (4)	04 Sep 2020 18:57:47

US3462076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:48

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered '11:45'	Savannah Peterson (b) (4)	04 Sep 2020 18:57:47

US3462076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:48

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered '04 Sep 2020 11:45'	System	04 Sep 2020 18:57:47

US3462076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:48

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered 'Left Arm (LEFT ARM)'	Savannah Peterson (b) (4)	04 Sep 2020 18:57:47

US3462076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:48

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'ONCE'	System	04 Sep 2020 18:57:47

US3462076

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:51:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 18:57:47

US3462076

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 23:19:43

US3462076

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered '04 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:19:43



US3462076

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered '11:25'	(b) (4), (b) (6)	10 Sep 2020 23:19:43

US3462076

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:48

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered '04 Sep 2020 11:25'	System	10 Sep 2020 23:19:43

US3462076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:51:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 17Aug2020 is reported in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 09:41:31
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 17Aug2020 is reported in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'updated' (Site from DM).	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:18:42
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 17Aug2020 is reported in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:14:40
User entered '04 Sep 2020'		10 Sep 2020 23:20:01

**US3462076**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:51:48**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		10 Sep 2020 23:20:01

US3462076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:51:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:20:01

US3462076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:51:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '11:28'	(b) (4), (b) (6)	10 Sep 2020 23:20:01

**US3462076**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:51:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered '04 Sep 2020 11:28'	System	10 Sep 2020 23:20:01

**US3462076**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:51:48**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		10 Sep 2020 23:20:01



US3462076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:51:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:36:26
User entered 'Yes (Y)'		10 Sep 2020 23:20:01

US3462076

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:51:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:36:26
User entered '11:28'		10 Sep 2020 23:20:01

**US3462076**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:51:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered empty.	System	09 Oct 2020 18:36:26
User entered '04 Sep 2020 11:28'	System	10 Sep 2020 23:20:01

US3462076

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 23:20:06

**US3462076**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:51:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered '1'	System	10 Sep 2020 23:20:06

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	04 Sep 2020 18:57:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T12:18:22', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '92925ad1-45ca-4adb-bd66-4d6481fd9aae'	System	04 Sep 2020 19:18:36
User entered 'Yes (Y)'	System	04 Sep 2020 19:18:36

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T12:18:25', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '92925ad1-45ca-4adb-bd66-4d6481fd9aae'	System	04 Sep 2020 19:18:36
User entered '98.6'	System	04 Sep 2020 19:18:36



US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T12:18:28', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '92925ad1-45ca-4adb-bd66-4d6481fd9aae'	System	04 Sep 2020 19:18:36
User entered 'No (N)'	System	04 Sep 2020 19:18:36

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T12:18:30', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '92925ad1-45ca-4adb-bd66-4d6481fd9aae'	System	04 Sep 2020 19:18:36
User entered '04 Sep 2020 12:18'	System	04 Sep 2020 19:18:36

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '04 Sep 2020 12:05'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '04 Sep 2020 14:35'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	04 Sep 2020 18:57:47
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T19:38:50', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '939c7c38-5481-4db3-befc-640b5e8aea13'	System	05 Sep 2020 02:39:08
User entered 'Yes (Y)'	System	05 Sep 2020 02:39:08

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T19:38:54', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '939c7c38-5481-4db3-befc-640b5e8aea13'	System	05 Sep 2020 02:39:08
User entered '98.6'	System	05 Sep 2020 02:39:08

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T19:38:58', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '939c7c38-5481-4db3-befc-640b5e8aea13'	System	05 Sep 2020 02:39:08
User entered 'Yes (Y)'	System	05 Sep 2020 02:39:08



US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	(b) (4)	13 Nov 2020 14:19:51
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Savannah Peterson (b) (4)	05 Nov 2020 21:47:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T19:39:01', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '939c7c38-5481-4db3-befc-640b5e8aea13'	(b) (4)	
User entered '1'	System	05 Sep 2020 02:39:08
	System	05 Sep 2020 02:39:08
	System	05 Sep 2020 02:39:08

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T19:39:01', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '939c7c38-5481-4db3-befc-640b5e8aea13'	System	05 Sep 2020 02:39:08
User entered '0'	System	05 Sep 2020 02:39:08

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T19:39:04', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '939c7c38-5481-4db3-befc-640b5e8aea13'	System	05 Sep 2020 02:39:08
User entered '04 Sep 2020 19:39'	System	05 Sep 2020 02:39:08

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '04 Sep 2020 15:30'	System	04 Sep 2020 18:57:47

**US3462076**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	04 Sep 2020 18:57:47
User entered 'Day 2'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:51:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-05T20:32:32', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '79919d8f-9896-4f2b-a10f-9244e6d87c3c'	System	06 Sep 2020 03:32:49
User entered 'Yes (Y)'	System	06 Sep 2020 03:32:49

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:51:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-05T20:32:35', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '79919d8f-9896-4f2b-a10f-9244e6d87c3c'	System	06 Sep 2020 03:32:49
User entered '99.4'	System	06 Sep 2020 03:32:49



US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-05T20:32:39', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '79919d8f-9896-4f2b-a10f-9244e6d87c3c'	System	06 Sep 2020 03:32:49
User entered 'Yes (Y)'	System	06 Sep 2020 03:32:49

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	(b) (4)	13 Nov 2020 14:19:54
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-05T20:32:42', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '79919d8f-9896-4f2b-a10f-9244e6d87c3c'	Savannah Peterson (b) (4)	05 Nov 2020 21:48:02
User entered '1'	System	06 Sep 2020 03:32:49
	System	06 Sep 2020 03:32:49
	System	06 Sep 2020 03:32:49

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:51:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-05T20:32:42', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '79919d8f-9896-4f2b-a10f-9244e6d87c3c'	System	06 Sep 2020 03:32:49
User entered '0'	System	06 Sep 2020 03:32:49

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:51:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-05T20:32:44', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '79919d8f-9896-4f2b-a10f-9244e6d87c3c'	System	06 Sep 2020 03:32:49
User entered '05 Sep 2020 20:32'	System	06 Sep 2020 03:32:49

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:51:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:51:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	04 Sep 2020 18:57:47
User entered 'Day 3'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:51:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-06T20:52:58', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '98f6836b-906c-47a7-88da-f5238aed6830'	System	07 Sep 2020 03:55:05
User entered 'Yes (Y)'	System	07 Sep 2020 03:55:05



US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:51:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-06T20:54:44', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '98f6836b-906c-47a7-88da-f5238aed6830'	System	07 Sep 2020 03:55:05
User entered '97.7'	System	07 Sep 2020 03:55:05

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-06T20:54:48', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '98f6836b-906c-47a7-88da-f5238aed6830'	System	07 Sep 2020 03:55:05
User entered 'Yes (Y)'	System	07 Sep 2020 03:55:05

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 14:19:58
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Savannah Peterson (b) (4)	05 Nov 2020 21:48:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-06T20:55:00', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '98f6836b-906c-47a7-88da-f5238aed6830'	(b) (4)	
User entered '1'	System	07 Sep 2020 03:55:05
	System	07 Sep 2020 03:55:05
	System	07 Sep 2020 03:55:05

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:51:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	(b) (4)	13 Nov 2020 14:20:01
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Savannah Peterson (b) (4)	05 Nov 2020 21:48:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-06T20:55:00', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '98f6836b-906c-47a7-88da-f5238aed6830'	(b) (4)	
User entered '1'	System	07 Sep 2020 03:55:05
	System	07 Sep 2020 03:55:05
	System	07 Sep 2020 03:55:05

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:51:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-06T20:55:03', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '98f6836b-906c-47a7-88da-f5238aed6830'	System	07 Sep 2020 03:55:05
User entered '06 Sep 2020 20:55'	System	07 Sep 2020 03:55:05

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:51:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:51:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	04 Sep 2020 18:57:47
User entered 'Day 4'	System	04 Sep 2020 18:57:47



US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:51:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-07T13:08:55', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'b0682d5e-fdd2-42b5-8ece-fcae91e762c1'	System	07 Sep 2020 20:09:07
User entered 'Yes (Y)'	System	07 Sep 2020 20:09:07

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:51:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-07T13:08:57', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'b0682d5e-fdd2-42b5-8ece-fcae91e762c1'	System	07 Sep 2020 20:09:07
User entered '98.3'	System	07 Sep 2020 20:09:07

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-07T13:09:00', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'b0682d5e-fdd2-42b5-8ece-fcae91e762c1'	System	07 Sep 2020 20:09:07
User entered 'No (N)'	System	07 Sep 2020 20:09:07

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:51:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-07T13:09:02', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'b0682d5e-fdd2-42b5-8ece-fcae91e762c1'	System	07 Sep 2020 20:09:07
User entered '07 Sep 2020 13:09'	System	07 Sep 2020 20:09:07

**US3462076**

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

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

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 18:57:47

**US3462076**

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

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

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:51:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	04 Sep 2020 18:57:47
User entered 'Day 5'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:51:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-08T12:02:22', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '2aa6cf51-3509-4435-8057-1386f82edd3d'	System	08 Sep 2020 19:02:51
User entered 'Yes (Y)'	System	08 Sep 2020 19:02:51



US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:51:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-08T12:02:42', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '2aa6cf51-3509-4435-8057-1386f82edd3d'	System	08 Sep 2020 19:02:51
User entered '99.2'	System	08 Sep 2020 19:02:51

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-08T12:02:45', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '2aa6cf51-3509-4435-8057-1386f82edd3d'	System	08 Sep 2020 19:02:51
User entered 'No (N)'	System	08 Sep 2020 19:02:51

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:51:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-08T12:02:47', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '2aa6cf51-3509-4435-8057-1386f82edd3d'	System	08 Sep 2020 19:02:51
User entered '08 Sep 2020 12:02'	System	08 Sep 2020 19:02:51

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:51:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 18:57:47

**US3462076**

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

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:51:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	04 Sep 2020 18:57:47
User entered 'Day 6'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:51:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:51:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17



US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:51:48

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

**US3462076**

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

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

**US3462076**

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

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 18:57:47

**US3462076**

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

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:51:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	04 Sep 2020 18:57:47
User entered 'Day 7'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:51:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-10T12:51:14', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '44c0a2c4-0971-4e58-82b3-48288f6d9700'	System	10 Sep 2020 19:51:26
User entered 'Yes (Y)'	System	10 Sep 2020 19:51:26



US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:51:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-10T12:51:16', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '44c0a2c4-0971-4e58-82b3-48288f6d9700'	System	10 Sep 2020 19:51:26
User entered '98.7'	System	10 Sep 2020 19:51:26

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-10T12:51:18', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '44c0a2c4-0971-4e58-82b3-48288f6d9700'	System	10 Sep 2020 19:51:26
User entered 'No (N)'	System	10 Sep 2020 19:51:26

US3462076

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:51:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-10T12:51:21', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '44c0a2c4-0971-4e58-82b3-48288f6d9700'	System	10 Sep 2020 19:51:26
User entered '10 Sep 2020 12:51'	System	10 Sep 2020 19:51:26

**US3462076**

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

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 18:57:47

**US3462076**

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

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	04 Sep 2020 18:57:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T12:18:34', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '498afdc2-b8c5-4715-935e-dacf52efcf11'	System	04 Sep 2020 19:18:54
User entered 'None (1)'	System	04 Sep 2020 19:18:54

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T12:18:45', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '498afdc2-b8c5-4715-935e-dacf52efcf11'	System	04 Sep 2020 19:18:54
User entered 'No (N)'	System	04 Sep 2020 19:18:54



US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T12:18:44', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '498afdc2-b8c5-4715-935e-dacf52efcf11'	System	04 Sep 2020 19:18:54
User entered 'No (N)'	System	04 Sep 2020 19:18:54

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T12:18:48', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '498afdc2-b8c5-4715-935e-dacf52efcf11'	System	04 Sep 2020 19:18:54
User entered 'None (1)'	System	04 Sep 2020 19:18:54

**US3462076**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T12:18:51', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '498afdc2-b8c5-4715-935e-dacf52efcf11'	System	04 Sep 2020 19:18:54
User entered '04 Sep 2020 12:18'	System	04 Sep 2020 19:18:54

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '04 Sep 2020 12:05'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '04 Sep 2020 14:35'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	04 Sep 2020 18:57:47
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T15:35:20', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'c10ffdea-af39-4a86-a02b-64577fe180b2'	System	04 Sep 2020 22:35:48
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 22:35:48

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T15:35:30', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'c10ffdea-af39-4a86-a02b-64577fe180b2'	System	04 Sep 2020 22:35:48
User entered 'No (N)'	System	04 Sep 2020 22:35:48



US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T15:35:39', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'c10ffdea-af39-4a86-a02b-64577fe180b2'	System	04 Sep 2020 22:35:48
User entered 'No (N)'	System	04 Sep 2020 22:35:48

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T15:35:41', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'c10ffdea-af39-4a86-a02b-64577fe180b2'	System	04 Sep 2020 22:35:48
User entered 'None (1)'	System	04 Sep 2020 22:35:48

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T15:35:44', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'c10ffdea-af39-4a86-a02b-64577fe180b2'	System	04 Sep 2020 22:35:48
User entered '04 Sep 2020 15:35'	System	04 Sep 2020 22:35:48

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '04 Sep 2020 15:30'	System	04 Sep 2020 18:57:47

**US3462076**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	04 Sep 2020 18:57:47
User entered 'Day 2'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-05T12:00:18', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '3d549c27-e918-43f5-8b64-dc40660630f2'	System	05 Sep 2020 19:00:48
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	05 Sep 2020 19:00:48

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-05T12:00:21', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '3d549c27-e918-43f5-8b64-dc40660630f2'	System	05 Sep 2020 19:00:48
User entered 'No (N)'	System	05 Sep 2020 19:00:48



US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-05T12:00:26', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '3d549c27-e918-43f5-8b64-dc40660630f2'	System	05 Sep 2020 19:00:48
User entered 'Yes (Y)'	System	05 Sep 2020 19:00:48

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:51:48

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-05T12:00:38', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '3d549c27-e918-43f5-8b64-dc40660630f2'	System	05 Sep 2020 19:00:48
User entered '1'	System	05 Sep 2020 19:00:48

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-05T12:00:41', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '3d549c27-e918-43f5-8b64-dc40660630f2'	System	05 Sep 2020 19:00:48
User entered 'None (1)'	System	05 Sep 2020 19:00:48

**US3462076**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-05T12:00:43', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '3d549c27-e918-43f5-8b64-dc40660630f2'	System	05 Sep 2020 19:00:48
User entered '05 Sep 2020 12:00'	System	05 Sep 2020 19:00:48

**US3462076**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:51:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	04 Sep 2020 18:57:47
User entered 'Day 3'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-06T20:41:07', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'cfef67a1-96b1-4106-a936-9fdf4c935a86'	System	07 Sep 2020 03:41:32
User entered 'Does not interfere with activity (2)'	System	07 Sep 2020 03:41:32



US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-06T20:41:09', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'cfef67a1-96b1-4106-a936-9fdf4c935a86'	System	07 Sep 2020 03:41:32
User entered 'No (N)'	System	07 Sep 2020 03:41:32

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-06T20:41:17', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'cfef67a1-96b1-4106-a936-9fdf4c935a86'	System	07 Sep 2020 03:41:32
User entered 'No (N)'	System	07 Sep 2020 03:41:32

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-06T20:41:21', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'cfef67a1-96b1-4106-a936-9fdf4c935a86'	System	07 Sep 2020 03:41:32
User entered 'None (1)'	System	07 Sep 2020 03:41:32

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:51:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-06T20:41:26', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'cfef67a1-96b1-4106-a936-9fdf4c935a86'	System	07 Sep 2020 03:41:32
User entered '06 Sep 2020 20:41'	System	07 Sep 2020 03:41:32

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:51:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 18:57:47

**US3462076**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	04 Sep 2020 18:57:47
User entered 'Day 4'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-07T13:09:40', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '0ca86360-f572-4708-8f71-b66127021aaa'	System	07 Sep 2020 20:09:51
User entered 'None (1)'	System	07 Sep 2020 20:09:51



US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-07T13:09:42', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '0ca86360-f572-4708-8f71-b66127021aaa'	System	07 Sep 2020 20:09:51
User entered 'No (N)'	System	07 Sep 2020 20:09:51

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-07T13:09:44', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '0ca86360-f572-4708-8f71-b66127021aaa'	System	07 Sep 2020 20:09:51
User entered 'No (N)'	System	07 Sep 2020 20:09:51

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-07T13:09:46', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '0ca86360-f572-4708-8f71-b66127021aaa'	System	07 Sep 2020 20:09:51
User entered 'None (1)'	System	07 Sep 2020 20:09:51

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:51:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-07T13:09:48', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '0ca86360-f572-4708-8f71-b66127021aaa'	System	07 Sep 2020 20:09:51
User entered '07 Sep 2020 13:09'	System	07 Sep 2020 20:09:51

**US3462076**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 18:57:47

**US3462076**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	04 Sep 2020 18:57:47
User entered 'Day 5'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-08T12:01:50', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'b859cc90-30fb-4760-927d-59c8f6e1e9dd'	System	08 Sep 2020 19:02:02
User entered 'None (1)'	System	08 Sep 2020 19:02:02



US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:51:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-08T12:01:51', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'b859cc90-30fb-4760-927d-59c8f6e1e9dd'	System	08 Sep 2020 19:02:02
User entered 'No (N)'	System	08 Sep 2020 19:02:02

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-08T12:01:53', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'b859cc90-30fb-4760-927d-59c8f6e1e9dd'	System	08 Sep 2020 19:02:02
User entered 'No (N)'	System	08 Sep 2020 19:02:02

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-08T12:01:54', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'b859cc90-30fb-4760-927d-59c8f6e1e9dd'	System	08 Sep 2020 19:02:02
User entered 'None (1)'	System	08 Sep 2020 19:02:02

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:51:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-08T12:01:57', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'b859cc90-30fb-4760-927d-59c8f6e1e9dd'	System	08 Sep 2020 19:02:02
User entered '08 Sep 2020 12:01'	System	08 Sep 2020 19:02:02

**US3462076**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 18:57:47

**US3462076**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	04 Sep 2020 18:57:47
User entered 'Day 6'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17



US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:51:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:51:48

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:51:48

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

**US3462076**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

**US3462076**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:51:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 18:57:47



US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:51:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	04 Sep 2020 18:57:47
User entered 'Day 7'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-10T12:51:24', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'fce7b572-f9ab-462c-b163-a0699053aa18'	System	10 Sep 2020 19:51:33
User entered 'None (1)'	System	10 Sep 2020 19:51:33

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:51:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-10T12:51:26', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'fce7b572-f9ab-462c-b163-a0699053aa18'	System	10 Sep 2020 19:51:33
User entered 'No (N)'	System	10 Sep 2020 19:51:33

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-10T12:51:27', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'fce7b572-f9ab-462c-b163-a0699053aa18'	System	10 Sep 2020 19:51:33
User entered 'No (N)'	System	10 Sep 2020 19:51:33

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:51:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-10T12:51:28', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'fce7b572-f9ab-462c-b163-a0699053aa18'	System	10 Sep 2020 19:51:33
User entered 'None (1)'	System	10 Sep 2020 19:51:33

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:51:48

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-10T12:51:30', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'fce7b572-f9ab-462c-b163-a0699053aa18'	System	10 Sep 2020 19:51:33
User entered '10 Sep 2020 12:51'	System	10 Sep 2020 19:51:33

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:51:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:51:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 18:57:47



US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	04 Sep 2020 18:57:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T12:18:55', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'b79d7f17-8f22-4dbe-8d6c-3d84298adc56'	System	04 Sep 2020 19:19:13
User entered 'None (0)'	System	04 Sep 2020 19:19:13

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T12:18:57', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'b79d7f17-8f22-4dbe-8d6c-3d84298adc56'	System	04 Sep 2020 19:19:13
User entered 'None (0)'	System	04 Sep 2020 19:19:13

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T12:18:58', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'b79d7f17-8f22-4dbe-8d6c-3d84298adc56'	System	04 Sep 2020 19:19:13
User entered 'None (0)'	System	04 Sep 2020 19:19:13

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T12:19:00', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'b79d7f17-8f22-4dbe-8d6c-3d84298adc56'	System	04 Sep 2020 19:19:13
User entered 'None (0)'	System	04 Sep 2020 19:19:13

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T12:19:01', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'b79d7f17-8f22-4dbe-8d6c-3d84298adc56'	System	04 Sep 2020 19:19:13
User entered 'None (0)'	System	04 Sep 2020 19:19:13

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T12:19:03', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'b79d7f17-8f22-4dbe-8d6c-3d84298adc56'	System	04 Sep 2020 19:19:13
User entered 'None (0)'	System	04 Sep 2020 19:19:13

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T12:19:05', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'b79d7f17-8f22-4dbe-8d6c-3d84298adc56'	System	04 Sep 2020 19:19:13
User entered 'No (N)'	System	04 Sep 2020 19:19:13



US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T12:19:07', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'b79d7f17-8f22-4dbe-8d6c-3d84298adc56'	System	04 Sep 2020 19:19:13
User entered '04 Sep 2020 12:19'	System	04 Sep 2020 19:19:13

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '04 Sep 2020 12:05'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:51:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '04 Sep 2020 14:35'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	04 Sep 2020 18:57:47
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T15:35:47', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'f4967c7e-64ed-47df-87c0-b7c2b591cbcd'	System	04 Sep 2020 22:36:11
User entered 'None (0)'	System	04 Sep 2020 22:36:11

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T15:35:50', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'f4967c7e-64ed-47df-87c0-b7c2b591cbcd'	System	04 Sep 2020 22:36:11
User entered 'No interference with activity (1)'	System	04 Sep 2020 22:36:11

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T15:35:55', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'f4967c7e-64ed-47df-87c0-b7c2b591cbcd'	System	04 Sep 2020 22:36:11
User entered 'Some interference with activity (2)'	System	04 Sep 2020 22:36:11

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T15:35:57', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'f4967c7e-64ed-47df-87c0-b7c2b591cbcd'	System	04 Sep 2020 22:36:11
User entered 'Some interference with activity (2)'	System	04 Sep 2020 22:36:11



US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T15:36:00', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'f4967c7e-64ed-47df-87c0-b7c2b591cbcd'	System	04 Sep 2020 22:36:11
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	04 Sep 2020 22:36:11

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T15:36:02', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'f4967c7e-64ed-47df-87c0-b7c2b591cbcd'	System	04 Sep 2020 22:36:11
User entered 'None (0)'	System	04 Sep 2020 22:36:11

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T15:36:04', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'f4967c7e-64ed-47df-87c0-b7c2b591cbcd'	System	04 Sep 2020 22:36:11
User entered 'No (N)'	System	04 Sep 2020 22:36:11

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:51:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-04T15:36:07', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'f4967c7e-64ed-47df-87c0-b7c2b591cbcd'	System	04 Sep 2020 22:36:11
User entered '04 Sep 2020 15:36'	System	04 Sep 2020 22:36:11

**US3462076**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '04 Sep 2020 15:30'	System	04 Sep 2020 18:57:47

**US3462076**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 18:57:47

**US3462076**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	04 Sep 2020 18:57:47
User entered 'Day 2'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:51:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-05T12:00:46', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '3381cf37-6e56-423d-81c1-73dd1a5a98d9'	System	05 Sep 2020 19:01:11
User entered 'None (0)'	System	05 Sep 2020 19:01:11



US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:51:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-05T12:00:48', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '3381cf37-6e56-423d-81c1-73dd1a5a98d9'	System	05 Sep 2020 19:01:11
User entered 'No interference with activity (1)'	System	05 Sep 2020 19:01:11

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:51:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-05T12:00:51', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '3381cf37-6e56-423d-81c1-73dd1a5a98d9'	System	05 Sep 2020 19:01:11
User entered 'No interference with activity (1)'	System	05 Sep 2020 19:01:11

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:51:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-05T12:00:52', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '3381cf37-6e56-423d-81c1-73dd1a5a98d9'	System	05 Sep 2020 19:01:11
User entered 'No interference with activity (1)'	System	05 Sep 2020 19:01:11

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:51:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-05T12:00:55', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '3381cf37-6e56-423d-81c1-73dd1a5a98d9'	System	05 Sep 2020 19:01:11
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	05 Sep 2020 19:01:11

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:51:48

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-05T12:01:00', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '3381cf37-6e56-423d-81c1-73dd1a5a98d9'	System	05 Sep 2020 19:01:11
User entered 'No interference with activity (1)'	System	05 Sep 2020 19:01:11

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-05T12:00:59', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '3381cf37-6e56-423d-81c1-73dd1a5a98d9'	System	05 Sep 2020 19:01:11
User entered 'No (N)'	System	05 Sep 2020 19:01:11

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:51:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-05T12:01:04', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '3381cf37-6e56-423d-81c1-73dd1a5a98d9'	System	05 Sep 2020 19:01:11
User entered '05 Sep 2020 12:01'	System	05 Sep 2020 19:01:11

**US3462076**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 18:57:47



US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:51:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	04 Sep 2020 18:57:47
User entered 'Day 3'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:51:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-06T20:41:31', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5400341f-a86b-452e-a5b3-608ecbb3978e'	System	07 Sep 2020 03:41:49
User entered 'None (0)'	System	07 Sep 2020 03:41:49

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:51:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-06T20:41:33', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5400341f-a86b-452e-a5b3-608ecbb3978e'	System	07 Sep 2020 03:41:49
User entered 'None (0)'	System	07 Sep 2020 03:41:49

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:51:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-06T20:41:36', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5400341f-a86b-452e-a5b3-608ecbb3978e'	System	07 Sep 2020 03:41:49
User entered 'None (0)'	System	07 Sep 2020 03:41:49

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:51:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-06T20:41:38', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5400341f-a86b-452e-a5b3-608ecbb3978e'	System	07 Sep 2020 03:41:49
User entered 'None (0)'	System	07 Sep 2020 03:41:49

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:51:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-06T20:41:41', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5400341f-a86b-452e-a5b3-608ecbb3978e'	System	07 Sep 2020 03:41:49
User entered 'None (0)'	System	07 Sep 2020 03:41:49

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:51:48

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-06T20:41:42', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5400341f-a86b-452e-a5b3-608ecbb3978e'	System	07 Sep 2020 03:41:49
User entered 'None (0)'	System	07 Sep 2020 03:41:49



US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-06T20:41:45', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5400341f-a86b-452e-a5b3-608ecbb3978e'	System	07 Sep 2020 03:41:49
User entered 'No (N)'	System	07 Sep 2020 03:41:49

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:51:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-06T20:41:47', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5400341f-a86b-452e-a5b3-608ecbb3978e'	System	07 Sep 2020 03:41:49
User entered '06 Sep 2020 20:41'	System	07 Sep 2020 03:41:49

**US3462076**

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

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

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 18:57:47

**US3462076**

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

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

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	04 Sep 2020 18:57:47
User entered 'Day 4'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:51:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-07T13:09:06', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '27913dd7-ee11-4730-830c-56a88d8b3fdb'	System	07 Sep 2020 20:09:40
User entered 'None (0)'	System	07 Sep 2020 20:09:40

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:51:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-07T13:09:08', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '27913dd7-ee11-4730-830c-56a88d8b3fdb'	System	07 Sep 2020 20:09:40
User entered 'None (0)'	System	07 Sep 2020 20:09:40

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:51:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-07T13:09:10', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '27913dd7-ee11-4730-830c-56a88d8b3fdb'	System	07 Sep 2020 20:09:40
User entered 'None (0)'	System	07 Sep 2020 20:09:40



US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:51:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-07T13:09:11', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '27913dd7-ee11-4730-830c-56a88d8b3fdb'	System	07 Sep 2020 20:09:40
User entered 'None (0)'	System	07 Sep 2020 20:09:40

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:51:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-07T13:09:13', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '27913dd7-ee11-4730-830c-56a88d8b3fdb'	System	07 Sep 2020 20:09:40
User entered 'None (0)'	System	07 Sep 2020 20:09:40

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:51:48

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-07T13:09:15', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '27913dd7-ee11-4730-830c-56a88d8b3fdb'	System	07 Sep 2020 20:09:40
User entered 'None (0)'	System	07 Sep 2020 20:09:40

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-07T13:09:34', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '27913dd7-ee11-4730-830c-56a88d8b3fdb'	System	07 Sep 2020 20:09:40
User entered 'No (N)'	System	07 Sep 2020 20:09:40

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:51:48

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-07T13:09:36', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '27913dd7-ee11-4730-830c-56a88d8b3fdb'	System	07 Sep 2020 20:09:40
User entered '07 Sep 2020 13:09'	System	07 Sep 2020 20:09:40

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:51:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 18:57:47

**US3462076**

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

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

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:51:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	04 Sep 2020 18:57:47
User entered 'Day 5'	System	04 Sep 2020 18:57:47



US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:51:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-08T12:02:06', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5d87cf81-99e8-46c1-af15-07af9b8d1191'	System	08 Sep 2020 19:02:22
User entered 'None (0)'	System	08 Sep 2020 19:02:22

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:51:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-08T12:02:07', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5d87cf81-99e8-46c1-af15-07af9b8d1191'	System	08 Sep 2020 19:02:22
User entered 'None (0)'	System	08 Sep 2020 19:02:22

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:51:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-08T12:02:08', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5d87cf81-99e8-46c1-af15-07af9b8d1191'	System	08 Sep 2020 19:02:22
User entered 'None (0)'	System	08 Sep 2020 19:02:22

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:51:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-08T12:02:09', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5d87cf81-99e8-46c1-af15-07af9b8d1191'	System	08 Sep 2020 19:02:22
User entered 'None (0)'	System	08 Sep 2020 19:02:22

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:51:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-08T12:02:10', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5d87cf81-99e8-46c1-af15-07af9b8d1191'	System	08 Sep 2020 19:02:22
User entered 'None (0)'	System	08 Sep 2020 19:02:22

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:51:48

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-08T12:02:12', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5d87cf81-99e8-46c1-af15-07af9b8d1191'	System	08 Sep 2020 19:02:22
User entered 'None (0)'	System	08 Sep 2020 19:02:22

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-08T12:02:15', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5d87cf81-99e8-46c1-af15-07af9b8d1191'	System	08 Sep 2020 19:02:22
User entered 'No (N)'	System	08 Sep 2020 19:02:22

**US3462076**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-08T12:02:16', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5d87cf81-99e8-46c1-af15-07af9b8d1191'	System	08 Sep 2020 19:02:22
User entered '08 Sep 2020 12:02'	System	08 Sep 2020 19:02:22



**US3462076**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 18:57:47

**US3462076**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	04 Sep 2020 18:57:47
User entered 'Day 6'	System	04 Sep 2020 18:57:47

**US3462076**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:51:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

**US3462076**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:51:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:51:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:51:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:51:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17



**US3462076**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:51:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

**US3462076**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

**US3462076**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:51:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 18:57:47

**US3462076**

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

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	04 Sep 2020 18:57:47
User entered 'Day 7'	System	04 Sep 2020 18:57:47

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:51:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-10T12:51:42', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'b9d92f22-1ae4-46d8-82e0-9135ab48b29d'	System	10 Sep 2020 19:51:57
User entered 'No interference with activity (1)'	System	10 Sep 2020 19:51:57

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:51:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-10T12:51:40', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'b9d92f22-1ae4-46d8-82e0-9135ab48b29d'	System	10 Sep 2020 19:51:57
User entered 'No interference with activity (1)'	System	10 Sep 2020 19:51:57



US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:51:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-10T12:51:38', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'b9d92f22-1ae4-46d8-82e0-9135ab48b29d'	System	10 Sep 2020 19:51:57
User entered 'None (0)'	System	10 Sep 2020 19:51:57

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:51:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-10T12:51:37', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'b9d92f22-1ae4-46d8-82e0-9135ab48b29d'	System	10 Sep 2020 19:51:57
User entered 'None (0)'	System	10 Sep 2020 19:51:57

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:51:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-10T12:51:36', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'b9d92f22-1ae4-46d8-82e0-9135ab48b29d'	System	10 Sep 2020 19:51:57
User entered 'None (0)'	System	10 Sep 2020 19:51:57

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:51:48

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-10T12:51:44', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'b9d92f22-1ae4-46d8-82e0-9135ab48b29d'	System	10 Sep 2020 19:51:57
User entered 'No interference with activity (1)'	System	10 Sep 2020 19:51:57

US3462076

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-10T12:51:46', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'b9d92f22-1ae4-46d8-82e0-9135ab48b29d'	System	10 Sep 2020 19:51:57
User entered 'No (N)'	System	10 Sep 2020 19:51:57

**US3462076**

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

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-09-10T12:51:52', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'b9d92f22-1ae4-46d8-82e0-9135ab48b29d'	System	10 Sep 2020 19:51:57
User entered '10 Sep 2020 12:51'	System	10 Sep 2020 19:51:57

**US3462076**

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

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 18:57:47

**US3462076**

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

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 18:57:47



US3462076

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	10 Sep 2020 19:51:57
User entered 'Day 8'	System	10 Sep 2020 19:51:57

US3462076

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:51:48

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

**US3462076**

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

**Form: Headache\_Day(8)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

**US3462076**

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

**Form: Headache\_Day(8)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 19:51:57

US3462076

Folder: Diary Dose 2 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:51:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 19:51:57

US3462076

Folder: Diary Dose 2 (1)

Form: Headache\_Day(9)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	10 Sep 2020 19:51:57
User entered 'Day 9'	System	10 Sep 2020 19:51:57

US3462076

Folder: Diary Dose 2 (1)

Form: Headache\_Day(9)

Generated On: 11 Aug 2021 22:51:48

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

**US3462076**

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

**Form: Headache\_Day(9)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17



US3462076

Folder: Diary Dose 2 (1)

Form: Headache\_Day(9)

Generated On: 11 Aug 2021 22:51:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 19:51:57

**US3462076**

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

**Form: Headache\_Day(9)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 19:51:57

US3462076

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:51:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	10 Sep 2020 19:51:57
User entered 'Day 8'	System	10 Sep 2020 19:51:57

US3462076

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:51:48

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

**US3462076**

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

**Form: Fatigue\_Day(8)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

**US3462076**

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

**Form: Fatigue\_Day(8)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 19:51:57

**US3462076**

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

**Form: Fatigue\_Day(8)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 19:51:57

US3462076

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	10 Sep 2020 19:51:57
User entered 'Day 9'	System	10 Sep 2020 19:51:57



US3462076

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 11 Aug 2021 22:51:48

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

**US3462076**

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

**Form: Fatigue\_Day(9)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

US3462076

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(9)

Generated On: 11 Aug 2021 22:51:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 19:51:57

**US3462076**

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

**Form: Fatigue\_Day(9)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 19:51:57

US3462076

Folder: Diary Dose 2 (1)

Form: Chills\_Day(8)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	10 Sep 2020 19:51:57
User entered 'Day 8'	System	10 Sep 2020 19:51:57

US3462076

Folder: Diary Dose 2 (1)

Form: Chills\_Day(8)

Generated On: 11 Aug 2021 22:51:48

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

**US3462076**

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

**Form: Chills\_Day(8)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 19:51:57

**US3462076**

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

**Form: Chills\_Day(8)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 19:51:57



**US3462076**

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

**Form: Chills\_Day(8)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

US3462076

Folder: Diary Dose 2 (1)

Form: Chills\_Day(9)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	10 Sep 2020 19:51:57
User entered 'Day 9'	System	10 Sep 2020 19:51:57

US3462076

Folder: Diary Dose 2 (1)

Form: Chills\_Day(9)

Generated On: 11 Aug 2021 22:51:48

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

**US3462076**

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

**Form: Chills\_Day(9)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 19:51:57

**US3462076**

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

**Form: Chills\_Day(9)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 19:51:57

**US3462076**

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

**Form: Chills\_Day(9)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

US3462076

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:51:48

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	10 Sep 2020 19:51:57
User entered 'Day 8'	System	10 Sep 2020 19:51:57

US3462076

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17



**US3462076**

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

**Form: Medical Attention\_Day(8)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

**US3462076**

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

**Form: Medical Attention\_Day(8)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 19:51:57

**US3462076**

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

**Form: Medical Attention\_Day(8)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 19:51:57

US3462076

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:51:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	10 Sep 2020 19:51:57
User entered 'Day 9'	System	10 Sep 2020 19:51:57

US3462076

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

**US3462076**

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

**Form: Medical Attention\_Day(9)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17

**US3462076**

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

**Form: Medical Attention\_Day(9)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 19:51:57

**US3462076**

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

**Form: Medical Attention\_Day(9)**

**Generated On: 11 Aug 2021 22:51:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 19:51:57



**US3462076**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:51:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	05 Nov 2020 22:11:08

US3462076

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '11 Sep 2020'	Savannah Peterson (b) (4)	05 Nov 2020 22:11:08

US3462076

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Contact Made (CONTACT MADE)'	Savannah Peterson (b) (4)	05 Nov 2020 22:11:08

US3462076

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:48

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 22:11:08

US3462076

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	05 Nov 2020 22:11:19

**US3462076**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:51:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'I'	System	05 Nov 2020 22:11:19

**US3462076**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:51:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	05 Nov 2020 22:11:55

US3462076

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '18 Sep 2020'	Savannah Peterson (b) (4)	05 Nov 2020 22:11:55



US3462076

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Contact Made (CONTACT MADE)'	Savannah Peterson (b) (4)	05 Nov 2020 22:11:55

US3462076

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:48

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 22:11:55

US3462076

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	05 Nov 2020 22:12:04

**US3462076**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:51:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'I'	System	05 Nov 2020 22:12:04

**US3462076**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:51:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	05 Nov 2020 22:12:25

US3462076

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered '25 Sep 2020'	Savannah Peterson (b) (4)	05 Nov 2020 22:12:25

US3462076

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Contact Made (CONTACT MADE)'	Savannah Peterson (b) (4)	05 Nov 2020 22:12:25

US3462076

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:48

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 22:12:25



US3462076

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:33
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	05 Nov 2020 22:12:32

**US3462076**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:51:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'I'	System	05 Nov 2020 22:12:32

US3462076

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	05 Nov 2020 22:13:13

US3462076

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:48

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered '09 Oct 2020'	Savannah Peterson (b) (4)	05 Nov 2020 22:13:13

US3462076

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered 'Clinic (Clinic)'	Savannah Peterson (b) (4)	05 Nov 2020 22:13:13

**US3462076**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:51:48**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'VISIT3'	System	05 Nov 2020 22:13:13

US3462076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered 'No (N)'	Savannah Peterson (b) (4)	05 Nov 2020 22:13:21

US3462076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 22:13:21



US3462076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 22:13:21

**US3462076**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered empty.	System	05 Nov 2020 22:13:21

US3462076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 22:13:21

US3462076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 22:13:21

US3462076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 22:13:21

US3462076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 22:13:21

**US3462076**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered empty.	System	05 Nov 2020 22:13:21

US3462076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 22:13:21



US3462076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered empty.	System	05 Nov 2020 22:13:21

US3462076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 22:13:21

US3462076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered empty.	System	05 Nov 2020 22:13:21

US3462076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 22:13:21

US3462076

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered empty.	System	05 Nov 2020 22:13:21

**US3462076**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57

**US3462076**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57

US3462076

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered 'No (N)'	Savannah Peterson (b) (4)	05 Nov 2020 22:13:28



US3462076

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 22:13:28

US3462076

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	05 Nov 2020 22:13:50

US3462076

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered '09 Oct 2020'	Savannah Peterson (b) (4)	05 Nov 2020 22:13:50

US3462076

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered '12:20'	Savannah Peterson (b) (4)	05 Nov 2020 22:13:50

**US3462076**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:51:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered '09 Oct 2020 12:20'	System	05 Nov 2020 22:13:50

US3462076

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 01:21:34
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	05 Nov 2020 22:13:57

**US3462076**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:51:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered '1'	System	05 Nov 2020 22:13:57

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 64'	System	07 Aug 2020 18:33:46



**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3462076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3462076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11



**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11



**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3462076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11



**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11
Data entry locked.	System	07 Aug 2020 18:33:46
User entered '07 Oct 2020 00:01'	System	07 Aug 2020 18:33:46

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11
Data entry locked.	System	07 Aug 2020 18:33:46
User entered '11 Oct 2020 23:59'	System	07 Aug 2020 18:33:46

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 71'	System	07 Aug 2020 18:33:46

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-10-15T00:25:06', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'de51059c-ab34-418e-9c0c-d7ce4e34978f'	System	15 Oct 2020 07:25:17
User entered 'No (N)'	System	15 Oct 2020 07:25:17

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-10-15T00:25:11', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'de51059c-ab34-418e-9c0c-d7ce4e34978f'	System	15 Oct 2020 07:25:17
User entered 'No (N)'	System	15 Oct 2020 07:25:17

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-10-15T00:25:15', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'de51059c-ab34-418e-9c0c-d7ce4e34978f'	System	15 Oct 2020 07:25:17
User entered '15 Oct 2020 00:25:15'	System	15 Oct 2020 07:25:17

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered '14 Oct 2020 00:01'	System	07 Aug 2020 18:33:46



**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered '18 Oct 2020 23:59'	System	07 Aug 2020 18:33:46

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 78'	System	07 Aug 2020 18:33:46

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-10-21T00:01:46', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '469f8bdd-d443-411c-b4fc-62054209b102'	System	21 Oct 2020 07:01:55
User entered 'No (N)'	System	21 Oct 2020 07:01:55

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-10-21T00:01:50', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '469f8bdd-d443-411c-b4fc-62054209b102'	System	21 Oct 2020 07:01:55
User entered 'No (N)'	System	21 Oct 2020 07:01:55

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-10-21T00:01:53', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '469f8bdd-d443-411c-b4fc-62054209b102'	System	21 Oct 2020 07:01:55
User entered '21 Oct 2020 00:01:53'	System	21 Oct 2020 07:01:55

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered '21 Oct 2020 00:01'	System	07 Aug 2020 18:33:46

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered '25 Oct 2020 23:59'	System	07 Aug 2020 18:33:46

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 92'	System	07 Aug 2020 18:33:46



**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-11-04T00:01:23', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5393f598-76c2-476b-9b0c-c863a2b37205'	System	04 Nov 2020 08:02:15
User entered 'Yes (Y)'	System	04 Nov 2020 08:02:15

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-11-04T00:01:28', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5393f598-76c2-476b-9b0c-c863a2b37205'	System	04 Nov 2020 08:02:15
User entered 'No (N)'	System	04 Nov 2020 08:02:15

US3462076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-11-04T00:01:32', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5393f598-76c2-476b-9b0c-c863a2b37205'	System	04 Nov 2020 08:02:15
User entered 'Yes (Y)'	System	04 Nov 2020 08:02:15

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-11-04T00:01:52', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5393f598-76c2-476b-9b0c-c863a2b37205'	System	04 Nov 2020 08:02:15
User entered '1'	System	04 Nov 2020 08:02:15

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-11-04T00:01:52', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5393f598-76c2-476b-9b0c-c863a2b37205'	System	04 Nov 2020 08:02:15
User entered '0'	System	04 Nov 2020 08:02:15

**US3462076**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-11-04T00:01:52', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5393f598-76c2-476b-9b0c-c863a2b37205'	System	04 Nov 2020 08:02:15
User entered '1'	System	04 Nov 2020 08:02:15

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-11-04T00:01:52', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5393f598-76c2-476b-9b0c-c863a2b37205'	System	04 Nov 2020 08:02:15
User entered '1'	System	04 Nov 2020 08:02:15

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-11-04T00:01:52', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5393f598-76c2-476b-9b0c-c863a2b37205'	System	04 Nov 2020 08:02:15
User entered '1'	System	04 Nov 2020 08:02:15



**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-11-04T00:01:52', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5393f598-76c2-476b-9b0c-c863a2b37205'	System	04 Nov 2020 08:02:15
User entered '1'	System	04 Nov 2020 08:02:15

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-11-04T00:01:52', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5393f598-76c2-476b-9b0c-c863a2b37205'	System	04 Nov 2020 08:02:15
User entered '1'	System	04 Nov 2020 08:02:15

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-11-04T00:01:52', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5393f598-76c2-476b-9b0c-c863a2b37205'	System	04 Nov 2020 08:02:15
User entered '1'	System	04 Nov 2020 08:02:15

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-11-04T00:01:52', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5393f598-76c2-476b-9b0c-c863a2b37205'	System	04 Nov 2020 08:02:15
User entered '1'	System	04 Nov 2020 08:02:15

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-11-04T00:01:52', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5393f598-76c2-476b-9b0c-c863a2b37205'	System	04 Nov 2020 08:02:15
User entered '0'	System	04 Nov 2020 08:02:15

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-11-04T00:01:52', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5393f598-76c2-476b-9b0c-c863a2b37205'	System	04 Nov 2020 08:02:15
User entered '0'	System	04 Nov 2020 08:02:15

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-11-04T00:01:52', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5393f598-76c2-476b-9b0c-c863a2b37205'	System	04 Nov 2020 08:02:15
User entered '1'	System	04 Nov 2020 08:02:15

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-11-04T00:01:52', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5393f598-76c2-476b-9b0c-c863a2b37205'	System	04 Nov 2020 08:02:15
User entered '1'	System	04 Nov 2020 08:02:15



**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-11-04T00:01:52', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5393f598-76c2-476b-9b0c-c863a2b37205'	System	04 Nov 2020 08:02:15
User entered '1'	System	04 Nov 2020 08:02:15

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-11-04T00:01:52', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5393f598-76c2-476b-9b0c-c863a2b37205'	System	04 Nov 2020 08:02:15
User entered '0'	System	04 Nov 2020 08:02:15

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-11-04T00:01:52', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5393f598-76c2-476b-9b0c-c863a2b37205'	System	04 Nov 2020 08:02:15
User entered '1'	System	04 Nov 2020 08:02:15

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-11-04T00:01:52', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5393f598-76c2-476b-9b0c-c863a2b37205'	System	04 Nov 2020 08:02:15
User entered '1'	System	04 Nov 2020 08:02:15

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-11-04T00:01:58', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5393f598-76c2-476b-9b0c-c863a2b37205'	System	04 Nov 2020 08:02:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Nov 2020 08:02:15

US3462076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-11-04T00:02:02', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5393f598-76c2-476b-9b0c-c863a2b37205'	System	04 Nov 2020 08:02:15
User entered 'No (N)'	System	04 Nov 2020 08:02:15

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-11-04T00:02:06', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5393f598-76c2-476b-9b0c-c863a2b37205'	System	04 Nov 2020 08:02:15
User entered '04 Nov 2020 00:02:06'	System	04 Nov 2020 08:02:15

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered '04 Nov 2020 00:01'	System	07 Aug 2020 18:33:46



**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:12:17
Data entry locked.	System	07 Aug 2020 18:33:46
User entered '08 Nov 2020 23:59'	System	07 Aug 2020 18:33:46

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 99'	System	07 Aug 2020 18:33:46

US3462076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3462076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3462076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11



US3462076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11
Data entry locked.	System	07 Aug 2020 18:33:46
User entered '11 Nov 2020 00:01'	System	07 Aug 2020 18:33:46

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11
Data entry locked.	System	07 Aug 2020 18:33:46
User entered '15 Nov 2020 23:59'	System	07 Aug 2020 18:33:46

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11
Data entry locked.	System	07 Aug 2020 18:33:46
User entered 'Day 106'	System	07 Aug 2020 18:33:46

US3462076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3462076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3462076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

US3462076

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:51:48

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11

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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11
Data entry locked.	System	07 Aug 2020 18:33:46
User entered '18 Nov 2020 00:01'	System	07 Aug 2020 18:33:46



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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:57:11
Data entry locked.	System	07 Aug 2020 18:33:46
User entered '22 Nov 2020 23:59'	System	07 Aug 2020 18:33:46

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[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 (5a31fd9b5c019591)', Time: '2020-11-23T10:53:31', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5ed53fe3-a17d-4ce9-9382-6e91b14a0c6d'	System	23 Nov 2020 18:53:35
User entered 'No (N)'	System	23 Nov 2020 18:53:35

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Have you been exposed to someone with 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 (5a31fd9b5c019591)', Time: '2020-11-23T10:53:30', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5ed53fe3-a17d-4ce9-9382-6e91b14a0c6d'	System	23 Nov 2020 18:53:35
User entered 'No (N)'	System	23 Nov 2020 18:53:35

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 22:51:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-11-23T10:53:34', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '5ed53fe3-a17d-4ce9-9382-6e91b14a0c6d' User entered '23 Nov 2020 10:53:34'	System	23 Nov 2020 18:53:35

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 15:57:11

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:57:11



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[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 (5a31fd9b5c019591)', Time: '2020-12-07T15:00:20', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '0cd9fa5b-50c9-4e0c-9817-211a83177e2c'	System	07 Dec 2020 23:00:29
User entered 'No (N)'	System	07 Dec 2020 23:00:29

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Have you been exposed to someone with 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 (5a31fd9b5c019591)', Time: '2020-12-07T15:00:23', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '0cd9fa5b-50c9-4e0c-9817-211a83177e2c'	System	07 Dec 2020 23:00:29
User entered 'No (N)'	System	07 Dec 2020 23:00:29

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**Folder: New Safety Follow Up Diary (1)**

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-12-07T15:00:26', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '0cd9fa5b-50c9-4e0c-9817-211a83177e2c'	System	07 Dec 2020 23:00:29
User entered '07 Dec 2020 15:00:26'	System	07 Dec 2020 23:00:29

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 15:57:11

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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 15:57:11



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[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 (5a31fd9b5c019591)', Time: '2020-12-13T00:01:20', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '2f5d11df-4ea7-4b89-ab29-b08018f5eb1f'	System	13 Dec 2020 08:01:27
User entered 'No (N)'	System	13 Dec 2020 08:01:27

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

Have you been exposed to someone with 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 (5a31fd9b5c019591)', Time: '2020-12-13T00:01:22', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '2f5d11df-4ea7-4b89-ab29-b08018f5eb1f'	System	13 Dec 2020 08:01:27
User entered 'No (N)'	System	13 Dec 2020 08:01:27

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-12-13T00:01:25', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '2f5d11df-4ea7-4b89-ab29-b08018f5eb1f' User entered '13 Dec 2020 00:01:25'	System	13 Dec 2020 08:01:27
	System	13 Dec 2020 08:01:27

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 15:57:11

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[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 (5a31fd9b5c019591)', Time: '2020-12-27T00:01:23', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '2247d1aa-7c4e-496d-a771-9f8ea0df7804'	System	27 Dec 2020 08:01:39
User entered 'No (N)'	System	27 Dec 2020 08:01:39

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

Have you been exposed to someone with 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 (5a31fd9b5c019591)', Time: '2020-12-27T00:01:34', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '2247d1aa-7c4e-496d-a771-9f8ea0df7804'	System	27 Dec 2020 08:01:39
User entered 'No (N)'	System	27 Dec 2020 08:01:39

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2020-12-27T00:01:37', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '2247d1aa-7c4e-496d-a771-9f8ea0df7804'	System	27 Dec 2020 08:01:39
User entered '27 Dec 2020 00:01:37'	System	27 Dec 2020 08:01:39

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 15:57:11

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[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 (5a31fd9b5c019591)', Time: '2021-01-05T14:32:10', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '64828749-3804-4310-b6c8-28c7fe4da798'	System	05 Jan 2021 22:32:18
User entered 'No (N)'	System	05 Jan 2021 22:32:18

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

Have you been exposed to someone with 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 (5a31fd9b5c019591)', Time: '2021-01-05T14:32:12', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '64828749-3804-4310-b6c8-28c7fe4da798'	System	05 Jan 2021 22:32:18
User entered 'No (N)'	System	05 Jan 2021 22:32:18

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-01-05T14:32:14', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '64828749-3804-4310-b6c8-28c7fe4da798'	System	05 Jan 2021 22:32:18
User entered '05 Jan 2021 14:32:14'	System	05 Jan 2021 22:32:18

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[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 (5a31fd9b5c019591)', Time: '2021-01-12T13:01:21', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '77512e0e-25ba-43db-95b7-0897445c7feb'	System	12 Jan 2021 21:01:31
User entered 'No (N)'	System	12 Jan 2021 21:01:31

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

Have you been exposed to someone with 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 (5a31fd9b5c019591)', Time: '2021-01-12T13:01:23', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '77512e0e-25ba-43db-95b7-0897445c7feb'	System	12 Jan 2021 21:01:31
User entered 'No (N)'	System	12 Jan 2021 21:01:31



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-01-12T13:01:26', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '77512e0e-25ba-43db-95b7-0897445c7feb'	System	12 Jan 2021 21:01:31
User entered '12 Jan 2021 13:01:26'	System	12 Jan 2021 21:01:31

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[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 (5a31fd9b5c019591)', Time: '2021-02-14T12:05:51', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '1bca6153-94be-4e72-8825-f4b2ec99a8db'	System	14 Feb 2021 20:06:36
User entered 'Yes (Y)'	System	14 Feb 2021 20:06:36

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

Have you been exposed to someone with 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 (5a31fd9b5c019591)', Time: '2021-02-14T12:05:55', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '1bca6153-94be-4e72-8825-f4b2ec99a8db'	System	14 Feb 2021 20:06:36
User entered 'No (N)'	System	14 Feb 2021 20:06:36

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-02-14T12:05:59', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '1bca6153-94be-4e72-8825-f4b2ec99a8db'	System	14 Feb 2021 20:06:36
User entered 'Yes (Y)'	System	14 Feb 2021 20:06:36

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-02-14T12:06:15', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '1bca6153-94be-4e72-8825-f4b2ec99a8db'	System	14 Feb 2021 20:06:36
User entered '0'	System	14 Feb 2021 20:06:36

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-02-14T12:06:15', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '1bca6153-94be-4e72-8825-f4b2ec99a8db'	System	14 Feb 2021 20:06:36
User entered '1'	System	14 Feb 2021 20:06:36

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-02-14T12:06:15', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '1bca6153-94be-4e72-8825-f4b2ec99a8db'	System	14 Feb 2021 20:06:36
User entered '0'	System	14 Feb 2021 20:06:36

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-02-14T12:06:15', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '1bca6153-94be-4e72-8825-f4b2ec99a8db'	System	14 Feb 2021 20:06:36
User entered '1'	System	14 Feb 2021 20:06:36

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-02-14T12:06:15', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '1bca6153-94be-4e72-8825-f4b2ec99a8db'	System	14 Feb 2021 20:06:36
User entered '1'	System	14 Feb 2021 20:06:36



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-02-14T12:06:15', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '1bca6153-94be-4e72-8825-f4b2ec99a8db'	System	14 Feb 2021 20:06:36
User entered '1'	System	14 Feb 2021 20:06:36

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-02-14T12:06:15', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '1bca6153-94be-4e72-8825-f4b2ec99a8db'	System	14 Feb 2021 20:06:36
User entered '1'	System	14 Feb 2021 20:06:36

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-02-14T12:06:15', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '1bca6153-94be-4e72-8825-f4b2ec99a8db' User entered '1'	System	14 Feb 2021 20:06:36

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-02-14T12:06:15', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '1bca6153-94be-4e72-8825-f4b2ec99a8db'	System	14 Feb 2021 20:06:36
User entered '1'	System	14 Feb 2021 20:06:36

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-02-14T12:06:15', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '1bca6153-94be-4e72-8825-f4b2ec99a8db'	System	14 Feb 2021 20:06:36
User entered '0'	System	14 Feb 2021 20:06:36

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-02-14T12:06:15', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '1bca6153-94be-4e72-8825-f4b2ec99a8db'	System	14 Feb 2021 20:06:36
User entered '0'	System	14 Feb 2021 20:06:36

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-02-14T12:06:15', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '1bca6153-94be-4e72-8825-f4b2ec99a8db'	System	14 Feb 2021 20:06:36
User entered '0'	System	14 Feb 2021 20:06:36

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-02-14T12:06:15', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '1bca6153-94be-4e72-8825-f4b2ec99a8db'	System	14 Feb 2021 20:06:36
User entered '1'	System	14 Feb 2021 20:06:36



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-02-14T12:06:15', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '1bca6153-94be-4e72-8825-f4b2ec99a8db'	System	14 Feb 2021 20:06:36
User entered '1'	System	14 Feb 2021 20:06:36

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-02-14T12:06:15', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '1bca6153-94be-4e72-8825-f4b2ec99a8db'	System	14 Feb 2021 20:06:36
User entered '1'	System	14 Feb 2021 20:06:36

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-02-14T12:06:15', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '1bca6153-94be-4e72-8825-f4b2ec99a8db'	System	14 Feb 2021 20:06:36
User entered '1'	System	14 Feb 2021 20:06:36

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-02-14T12:06:15', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '1bca6153-94be-4e72-8825-f4b2ec99a8db'	System	14 Feb 2021 20:06:36
User entered '0'	System	14 Feb 2021 20:06:36

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-02-14T12:06:18', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '1bca6153-94be-4e72-8825-f4b2ec99a8db'	System	14 Feb 2021 20:06:36
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Feb 2021 20:06:36

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-02-14T12:06:22', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '1bca6153-94be-4e72-8825-f4b2ec99a8db'	System	14 Feb 2021 20:06:36
User entered 'No (N)'	System	14 Feb 2021 20:06:36

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-02-14T12:06:25', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '1bca6153-94be-4e72-8825-f4b2ec99a8db' User entered '14 Feb 2021 12:06:25'	System	14 Feb 2021 20:06:36

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[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 (5a31fd9b5c019591)', Time: '2021-02-21T00:01:43', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '42a41a50-8cbb-4b61-8b2a-f1b1193aebfb'	System	21 Feb 2021 08:01:49
User entered 'No (N)'	System	21 Feb 2021 08:01:49

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

Have you been exposed to someone with 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 (5a31fd9b5c019591)', Time: '2021-02-21T00:01:45', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '42a41a50-8cbb-4b61-8b2a-f1b1193aebfb'	System	21 Feb 2021 08:01:49
User entered 'No (N)'	System	21 Feb 2021 08:01:49

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-02-21T00:01:47', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '42a41a50-8cbb-4b61-8b2a-f1b1193aebfb'	System	21 Feb 2021 08:01:49
User entered '21 Feb 2021 00:01:47'	System	21 Feb 2021 08:01:49

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[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 (5a31fd9b5c019591)', Time: '2021-02-28T01:48:34-08:00', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '85be85dd-dec6-418e-8750-d0230520587e' User entered 'No (N)'	System	28 Feb 2021 09:48:42

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

Have you been exposed to someone with 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 (5a31fd9b5c019591)', Time: '2021-02-28T01:48:36-08:00', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '85be85dd-dec6-418e-8750-d0230520587e'	System	28 Feb 2021 09:48:42
User entered 'No (N)'	System	28 Feb 2021 09:48:42

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-02-28T01:48:39-08:00', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '85be85dd-dec6-418e-8750-d0230520587e' User entered '28 Feb 2021 01:48:39'	System	28 Feb 2021 09:48:42
	System	28 Feb 2021 09:48:42

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[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 (5a31fd9b5c019591)', Time: '2021-03-16T15:23:39-07:00', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'e3d4b903-6cf7-476e-82d0-a217cb979ecd'	System	16 Mar 2021 22:23:48
User entered 'No (N)'	System	16 Mar 2021 22:23:48

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

Have you been exposed to someone with 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 (5a31fd9b5c019591)', Time: '2021-03-16T15:23:41-07:00', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'e3d4b903-6cf7-476e-82d0-a217cb979ecd'	System	16 Mar 2021 22:23:48
User entered 'No (N)'	System	16 Mar 2021 22:23:48

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-03-16T15:23:43-07:00', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'e3d4b903-6cf7-476e-82d0-a217cb979ecd' User entered '16 Mar 2021 15:23:43'	System	16 Mar 2021 22:23:48
	System	16 Mar 2021 22:23:48

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[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 (5a31fd9b5c019591)', Time: '2021-03-21T00:01:22-07:00', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '8621165e-5738-46ad-b1a1-88d8ed21c201'	System	21 Mar 2021 07:01:31
User entered 'No (N)'	System	21 Mar 2021 07:01:31



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

Have you been exposed to someone with 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 (5a31fd9b5c019591)', Time: '2021-03-21T00:01:26-07:00', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '8621165e-5738-46ad-b1a1-88d8ed21c201'	System	21 Mar 2021 07:01:31
User entered 'No (N)'	System	21 Mar 2021 07:01:31

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-03-21T00:01:28-07:00', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '8621165e-5738-46ad-b1a1-88d8ed21c201'	System	21 Mar 2021 07:01:31
User entered '21 Mar 2021 00:01:28'	System	21 Mar 2021 07:01:31

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[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 (5a31fd9b5c019591)', Time: '2021-04-13T00:22:12-07:00', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'ca294cc7-0d9a-4b62-a01a-951644aba21d' User entered 'No (N)'	System	13 Apr 2021 07:22:19
	System	13 Apr 2021 07:22:19

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

Have you been exposed to someone with 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 (5a31fd9b5c019591)', Time: '2021-04-13T00:22:14-07:00', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'ca294cc7-0d9a-4b62-a01a-951644aba21d'	System	13 Apr 2021 07:22:19
User entered 'No (N)'	System	13 Apr 2021 07:22:19

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-04-13T00:22:17-07:00', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: 'ca294cc7-0d9a-4b62-a01a-951644aba21d'	System	13 Apr 2021 07:22:19
User entered '13 Apr 2021 00:22:17'	System	13 Apr 2021 07:22:19

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[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 (5a31fd9b5c019591)', Time: '2021-04-19T00:30:30-07:00', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '16e674c9-4121-4c62-b22f-e812680eea2d' User entered 'No (N)'	System	19 Apr 2021 07:30:40
	System	19 Apr 2021 07:30:40

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

Have you been exposed to someone with 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 (5a31fd9b5c019591)', Time: '2021-04-19T00:30:32-07:00', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '16e674c9-4121-4c62-b22f-e812680eea2d'	System	19 Apr 2021 07:30:40
User entered 'No (N)'	System	19 Apr 2021 07:30:40

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-04-19T00:30:34-07:00', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '16e674c9-4121-4c62-b22f-e812680eea2d' User entered '19 Apr 2021 00:30:34'	System	19 Apr 2021 07:30:40
	System	19 Apr 2021 07:30:40

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 15:57:11



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 15:57:11



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 15:57:11



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 15:57:11



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 15:57:11



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 15:57:11



**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 15:57:11

**US3462076**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:51:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:57:11
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 15:57:11

US3462076

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:51:48**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-02-28T01:48:46-08:00', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '7baa3402-42d5-41eb-93c5-5cbc7b32370f'	System	28 Feb 2021 09:48:50
User entered 'No (N)'	System	28 Feb 2021 09:48:50

**US3462076**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:51:48**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 12:41:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5a31fd9b5c019591)', Time: '2021-02-28T01:48:49-08:00', User OID: 'PatientReportedOutcome (US3462076)', ODM File OID: '7baa3402-42d5-41eb-93c5-5cbc7b32370f' User entered '28 Feb 2021 01:48:49'	System	28 Feb 2021 09:48:50
	System	28 Feb 2021 09:48:50

**US3462076**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:51:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	05 Nov 2020 22:14:26



US3462076

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '30 Oct 2020'	Savannah Peterson (b) (4)	05 Nov 2020 22:14:26

US3462076

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Contact Made (CONTACT MADE)'	Savannah Peterson (b) (4)	05 Nov 2020 22:14:26

US3462076

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:48

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 22:14:26

US3462076

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	05 Nov 2020 22:14:34

**US3462076**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:51:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 01:57:57
User entered 'I'	System	05 Nov 2020 22:14:34

**US3462076**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:51:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:56:25
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:06:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:39:16

**US3462076**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:51:48**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:56:25
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:06:48
User entered '07 Dec 2020'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:39:16

**US3462076**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:51:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:56:25
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:06:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:39:16



**US3462076**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:51:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:56:25
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:06:48
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:39:16

**US3462076**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:51:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:56:25
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:06:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:39:19

**US3462076**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:51:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:56:25
User entered 'I'	System	25 Mar 2021 17:39:19

**US3462076**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:51:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:56:25
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:06:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:39:51

US3462076

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:56:25
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:06:48
User entered '05 Jan 2021'	(b) (4) (o) (4), (b) (6)	25 Mar 2021 17:39:51

**US3462076**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:51:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:56:25
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:06:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:39:51

US3462076

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:48

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:56:25
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:06:48
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:39:51

US3462076

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:56:25
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:06:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:39:54



**US3462076**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:51:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:56:25
User entered 'I'	System	25 Mar 2021 17:39:54

US3462076

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:51:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:56:25
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:18
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4)	07 Apr 2021 19:02:22
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	25 Mar 2021 17:40:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Mar 2021 17:40:11

**US3462076**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:51:48**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:56:25
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:18
User entered '4 Feb 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:02:22
User entered empty.		25 Mar 2021 17:40:11

**US3462076**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:51:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:56:25
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:18
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:02:22
User entered empty.		25 Mar 2021 17:40:11

**US3462076**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:51:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:56:25
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 13:15:18
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:40:11

US3462076

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:56:25
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:06:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:40:16

**US3462076**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:51:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:56:25
User entered 'I'	System	25 Mar 2021 17:40:16

**US3462076**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:51:48**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:25
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:06:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:40:31



**US3462076**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:51:48**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:25
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:06:48
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:40:31

US3462076

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:48

[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 07:59:25
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:06:48
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:40:31

**US3462076**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:51:48**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:25
User entered 'VISIT4'	System	25 Mar 2021 17:40:31

US3462076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:25
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:03:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:06:49

US3462076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:25
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:03:59
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:06:49

US3462076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:25
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:03:59
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:06:49

US3462076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:25
User entered empty.	System	01 Apr 2021 16:06:49

US3462076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:25
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:03:59
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:06:49



US3462076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:25
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:03:59
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:06:49

US3462076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:25
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:03:59
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:06:49

**US3462076**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:25
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:03:59
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:06:49

**US3462076**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:25
User entered empty.	System	01 Apr 2021 16:06:49

US3462076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:25
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:03:59
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 16:06:49

US3462076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:25
User entered empty.	System	01 Apr 2021 16:06:49

US3462076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:25
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:03:59
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:06:49

**US3462076**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:25
User entered empty.	System	01 Apr 2021 16:06:49



US3462076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:25
User signature succeeded.	Gregg Lucksinger (b) (4)	01 Apr 2021 19:03:59
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 16:06:49

US3462076

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:25
User entered empty.	System	01 Apr 2021 16:06:49

**US3462076**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:25

**US3462076**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:25

US3462076

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:25
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:06:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:40:36

US3462076

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:51:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:25
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:06:48
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:40:36

US3462076

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:25
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:06:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:40:48

US3462076

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:25
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:06:48
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:40:48



US3462076

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:25
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:06:48
User entered '15:40'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:40:48

**US3462076**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:51:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:25
User entered '16 Mar 2021 15:40'	System	25 Mar 2021 17:40:48

US3462076

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:51:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:25
User signature succeeded.	Gregg Lucksinger (b) (4)	25 Mar 2021 22:06:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:40:51

**US3462076**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:51:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:59:25
User entered '1'	System	25 Mar 2021 17:40:51

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:51:48

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:14
DataPoint Verified.		20 Apr 2021 21:22:12
DataPoint Un-verified.		20 Apr 2021 21:22:10
DataPoint Verified.		20 Apr 2021 21:12:36
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User closed query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 17 AUG 2020 is reported unde illness Visit Day 1 in PPD Central lab, however the same is missing in EDC.As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 08:55:42
Query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 17 AUG 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC.As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' answered with 'added missing data' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 17:52:38
User opened query ' Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 17 AUG 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC.As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).		10 Nov 2020 05:35:58
User entered '17 Aug 2020'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:52:46

**US3462076**

**Folder: Covid-19 Assessment 17 Aug 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:51:48**

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:14
DataPoint Verified.		20 Apr 2021 21:12:36
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered '08:00'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:52:46
	(b) (4)	

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:51:48

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:14
User entered '17 Aug 2020 08:00'	System	05 Nov 2020 21:52:46

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:51:48

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:14
DataPoint Verified.		20 Apr 2021 21:12:36
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4) Savannah Peterson (b) (4)	05 Nov 2020 21:52:46



US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:51:48

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:14
DataPoint Verified.		20 Apr 2021 21:12:36
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered 'Yes (Y)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:52:46
	(b) (4)	

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Day 1 (Day 1)'	Savannah Peterson (b) (4)	05 Nov 2020 21:55:48

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:24:57
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '17 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:58:55
User entered '15 Aug 2020'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:55:48
	(b) (4)	

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '0'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:55:48
	(b) (4)	

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered missing code ND - Not Done.	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:55:48
	(b) (4)	

**US3462076**

**Folder: Covid-19 Assessment 17 Aug 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:51:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
User entered '%'	System	05 Nov 2020 21:55:48

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '98.5' F	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:55:48
	(b) (4)	

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Moderate (Moderate)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:55:48



US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:51:52
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Moderate (Moderate)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:55:48
	(b) (4)	

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Moderate (Moderate)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:55:48

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Moderate (Moderate)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:55:48

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:51:07
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Moderate (Moderate)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:55:48

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Moderate (Moderate)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:55:48

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Moderate (Moderate)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:55:48

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:52:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:55:48
	(b) (4)	

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Moderate (Moderate)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:55:48



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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Moderate (Moderate)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:55:48

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Moderate (Moderate)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:55:48

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Moderate (Moderate)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:55:48

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Moderate (Moderate)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:55:48

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:55:48

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:55:48

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:51:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Moderate (Moderate)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:55:48

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Day 2 (Day 2)'	Savannah Peterson (b) (4)	05 Nov 2020 21:58:55



US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:48:10
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '18 Aug 2020'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:58:55
	(b) (4)	

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '0'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:58:55
	(b) (4)	

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:48:13
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '95'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:58:55

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
User entered '%'	System	05 Nov 2020 21:58:55

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:48

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:48:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '101.9' F	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:58:55
	(b) (4)	

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered empty.	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:58:55
	(b) (4)	

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
User signature succeeded.	Gregg Lucksinger (b) (4)	22 Apr 2021 16:08:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:21:21
User closed query 'Per source, Cough graded as 1 and EDC is None, please clarify?' (Site from CRA).		21 Apr 2021 19:21:00
Query 'Per source, Cough graded as 1 and EDC is None, please clarify?' answered with 'updated ' (Site from CRA).		21 Apr 2021 17:16:49
DataPoint Un-verified.		21 Apr 2021 17:16:07
Signature has been broken.		21 Apr 2021 17:16:07
User entered 'Mild (Mild)' reason for change: Data Entry Error		21 Apr 2021 17:16:07
DataPoint Verified.		20 Apr 2021 21:59:43
User opened query 'Per source, Cough graded as 1 and EDC is None, please clarify?' (Site from CRA).		20 Apr 2021 21:52:55
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:58:55

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Form: Symptom Log (2)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Mild (Mild)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:58:55
	(b) (4)	



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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Mild (Mild)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:58:55
	(b) (4)	

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Mild (Mild)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:58:55
	(b) (4)	

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Form: Symptom Log (2)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Mild (Mild)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:58:55

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**Folder: Covid-19 Assessment 17 Aug 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:51:48**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Mild (Mild)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:58:55
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:53:11
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:58:55

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Mild (Mild)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:58:55
	(b) (4)	

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Mild (Mild)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:58:55

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**Folder: Covid-19 Assessment 17 Aug 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:51:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Mild (Mild)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:58:55
	(b) (4)	



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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Mild (Mild)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:58:55

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Form: Symptom Log (2)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:58:55
	(b) (4)	

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (2)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:58:55

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Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:51:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:53:18
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:58:55
	(b) (4)	

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Form: Symptom Log (2)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:53:25
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Mild (Mild)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:58:55

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Day 3 (Day 3)'	Savannah Peterson (b) (4)	05 Nov 2020 22:00:38

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Form: Symptom Log (3)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:53:46
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '19 Aug 2020'	(b) (4) Savannah Peterson (b) (4)	05 Nov 2020 22:00:38
	(b) (4)	

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '0'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:00:38
	(b) (4)	



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Form: Symptom Log (3)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:53:54
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered missing code ND - Not Done.	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:00:38
	(b) (4)	

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**Folder: Covid-19 Assessment 17 Aug 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:51:48**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
User entered '%'	System	05 Nov 2020 22:00:38

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:53:56
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered missing code ND - Not Done.	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:00:38
	(b) (4)	

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Form: Symptom Log (3)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4)	05 Nov 2020 22:00:38
	(b) (4)	

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Form: Symptom Log (3)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:54:01
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Mild (Mild)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:00:38

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Form: Symptom Log (3)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:00:38
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:51:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:00:38
	(b) (4)	

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:51:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:00:38
	(b) (4)	



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Form: Symptom Log (3)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:00:38

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Form: Symptom Log (3)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:00:38
	(b) (4)	

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Form: Symptom Log (3)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:00:38

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Form: Symptom Log (3)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:00:38

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Form: Symptom Log (3)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:00:38

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**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:51:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Mild (Mild)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:00:38
	(b) (4)	

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:02:18
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:00:38
	(b) (4)	

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:00:38



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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:00:38
	(b) (4)	

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Form: Symptom Log (3)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 22:04:14
	(b) (4)	05 Nov 2020 22:00:38

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (3)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 22:04:14
	(b) (4)	05 Nov 2020 22:00:38

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Form: Symptom Log (4)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Day 4 (Day 4)'	Savannah Peterson (b) (4)	05 Nov 2020 22:02:18

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:56:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '20 Aug 2020'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:02:18
	(b) (4)	

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '0'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:02:18
	(b) (4)	

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:56:46
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '97'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:02:18
	(b) (4)	

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Form: Symptom Log (4)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
User entered '%'	System	05 Nov 2020 22:02:18



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Form: Symptom Log (4)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:56:49
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '99.0' F	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:02:18
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:48

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Un-verified.		20 Apr 2021 22:02:36
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:02:18

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:56:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Mild (Mild)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:02:18
	(b) (4)	

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Form: Symptom Log (4)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Un-verified.		20 Apr 2021 22:02:39
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4)	05 Nov 2020 22:02:18
	(b) (4)	

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Un-verified.		20 Apr 2021 22:02:42
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:02:18

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Un-verified.		20 Apr 2021 22:02:45
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4)	05 Nov 2020 22:02:18
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Un-verified.		20 Apr 2021 22:02:49
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:02:18

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Un-verified.		20 Apr 2021 22:02:50
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:02:18



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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Un-verified.		20 Apr 2021 22:02:53
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:02:18

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Un-verified.		20 Apr 2021 22:02:55
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:02:18

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Un-verified.		20 Apr 2021 22:02:56
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:02:18

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Un-verified.		20 Apr 2021 22:02:17
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Mild (Mild)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:02:18

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Un-verified.		20 Apr 2021 22:02:15
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Mild (Mild)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:02:18

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Form: Symptom Log (4)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Un-verified.		20 Apr 2021 22:03:01
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4)	05 Nov 2020 22:02:18
	(b) (4)	

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Form: Symptom Log (4)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Un-verified.		20 Apr 2021 22:03:17
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4)	05 Nov 2020 22:02:18
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Un-verified.		20 Apr 2021 22:03:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	05 Nov 2020 22:04:14
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 22:02:18
	(b) (4)	



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Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:51:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Un-verified.		20 Apr 2021 22:03:21
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	05 Nov 2020 22:04:14
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 22:02:18
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:51:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Day 5 (Day 5)'	Savannah Peterson (b) (4)	05 Nov 2020 22:04:14

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Generated On: 11 Aug 2021 22:51:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:58:34
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '21 Aug 2020'	(b) (4) Savannah Peterson (b) (4)	05 Nov 2020 22:04:14
	(b) (4)	

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '0'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:04:14
	(b) (4)	

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Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:51:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:58:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '99'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:04:14

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Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:51:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
User entered '%'	System	05 Nov 2020 22:04:14

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Form: Symptom Log (5)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:58:37
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '98.8' F	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:04:14
	(b) (4)	

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Form: Symptom Log (5)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:39
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:04:14
	(b) (4)	



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Form: Symptom Log (5)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:58:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:04:14
	(b) (4)	

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Form: Symptom Log (5)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:04:14
	(b) (4)	

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Form: Symptom Log (5)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:04:14

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Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:51:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:04:14
	(b) (4)	

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Form: Symptom Log (5)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:04:14

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Form: Symptom Log (5)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:04:14

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Form: Symptom Log (5)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:04:14
	(b) (4)	

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Form: Symptom Log (5)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:04:14



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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:04:14

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:04:14
	(b) (4)	

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:04:14

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:04:14
	(b) (4)	

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:04:14

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:04:14

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**Form: Symptom Log (5)**

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:06
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:04:14

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Day 6 (Day 6)'	Savannah Peterson (b) (4)	05 Nov 2020 22:06:07



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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '22 Aug 2020'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:06:07
	(b) (4)	

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '0'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:06:07
	(b) (4)	

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '100'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:06:07
	(b) (4)	

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Form: Symptom Log (6)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
User entered '%'	System	05 Nov 2020 22:06:07

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '98.5' F	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:06:07
	(b) (4)	

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:06:07

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:06:07
	(b) (4)	

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:06:07
	(b) (4)	



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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:06:07
	(b) (4)	

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Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:06:07

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:06:07
	(b) (4)	

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:48

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:06:07
	(b) (4)	

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:06:07
	(b) (4)	

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:06:07
	(b) (4)	

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:06:07

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**Folder: Covid-19 Assessment 17 Aug 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:51:48**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:06:07



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Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:06:07

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:06:07
	(b) (4)	

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Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:06:07
	(b) (4)	

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:06:07
	(b) (4)	

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:51:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:06:07
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:48

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Day 7 (Day 7)'	Savannah Peterson (b) (4)	05 Nov 2020 22:07:41

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:48

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '23 Aug 2020'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:07:41

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '0'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:07:41
	(b) (4)	



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Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '99'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:07:41
	(b) (4)	

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
User entered '%'	System	05 Nov 2020 22:07:41

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (7)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '98.7' F	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:07:41
	(b) (4)	

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**Folder: Covid-19 Assessment 17 Aug 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:51:48**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:07:41

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:48

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:07:41
	(b) (4)	

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Form: Symptom Log (7)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:07:41
	(b) (4)	

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:48

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:07:41
	(b) (4)	

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:48

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:07:41
	(b) (4)	



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Form: Symptom Log (7)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:07:41

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Form: Symptom Log (7)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:07:41
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:07:41

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:07:41
	(b) (4)	

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Form: Symptom Log (7)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:07:41

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:07:41

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:07:41

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:07:41
	(b) (4)	



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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:07:41
	(b) (4)	

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Form: Symptom Log (7)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:07:41
	(b) (4)	

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Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:51:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:07:41

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Form: Symptom Log (8)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Day 8 (Day 8)'	Savannah Peterson (b) (4)	05 Nov 2020 22:09:10

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '24 Aug 2020'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:09:10

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Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:48

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '0'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:09:10
	(b) (4)	

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Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:48

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '100'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:09:10
	(b) (4)	

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Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:48

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
User entered '%'	System	05 Nov 2020 22:09:10



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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '98.5' F	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:09:10
	(b) (4)	

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Form: Symptom Log (8)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:09:10

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Form: Symptom Log (8)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:09:10
	(b) (4)	

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Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:48

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:09:10
	(b) (4)	

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Form: Symptom Log (8)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:09:10

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (8)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:09:10
	(b) (4)	

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Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:48

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:09:10

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Form: Symptom Log (8)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:09:10
	(b) (4)	



US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:48

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:09:10

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:48

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:09:10
	(b) (4)	

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:48

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:09:10

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:48

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:09:10

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:48

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:09:10

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:48

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:09:10

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:48

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:09:10

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:48

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:09:10



US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:51:48

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:22
DataPoint Verified.		20 Apr 2021 21:59:43
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'None (None)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:09:10
	(b) (4)	

**US3462076**

**Folder: Covid-19 Assessment 17 Aug 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:51:48**

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:34
DataPoint Verified.		20 Apr 2021 22:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '17 Aug 2020'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:10:03

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:51:48

[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 10:50:34
DataPoint Verified.		20 Apr 2021 22:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Yes (Y)'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:10:03

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:51:48

[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 10:50:34
DataPoint Verified.		20 Apr 2021 22:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'No (N)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:10:03
	(b) (4)	

**US3462076**

**Folder: Covid-19 Assessment 17 Aug 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:51:48**

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:34
DataPoint Verified.		20 Apr 2021 22:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '17 Aug 2020'	(b) (4) Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 22:10:03

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:51:48

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:34
DataPoint Verified.		20 Apr 2021 22:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Savannah Peterson (b) (4)	05 Nov 2020 22:10:03

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:51:48

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:34
DataPoint Verified.		20 Apr 2021 22:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered empty.	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:10:03
	(b) (4)	

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:51:48

[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 10:50:34
DataPoint Verified.		20 Apr 2021 22:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'No (N)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:10:03
	(b) (4)	



US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:51:48

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:34
DataPoint Verified.		20 Apr 2021 22:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered empty.	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:10:03
	(b) (4)	

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:51:48

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:34
DataPoint Verified.		20 Apr 2021 22:07:58
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered empty.	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 22:10:03
	(b) (4)	

US3462076

Folder: Covid-19 Assessment 17 Aug 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:51:48

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:50:34
User entered '0'	System	05 Nov 2020 22:10:03

**US3462076**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:51:48**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
User accepted default value 'Day 3 (Day 3)'		24 Feb 2021 17:47:14

**US3462076**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:51:48**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:33:10
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:47:14

US3462076

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:51:48

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:33:10
User closed query 'Per CL Lab Recon: saliva: please confirm the collected date in EDC, since per PPD Lab the collection date is updated as 21AUG2020.Thanks' (Site from DM).		06 Apr 2021 08:32:31
Query 'Per CL Lab Recon: saliva: please confirm the collected date in EDC, since per PPD Lab the collection date is updated as 21AUG2020.Thanks' answered with 'Date is correct ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 22:58:14
User opened query 'Per CL Lab Recon: saliva: please confirm the collected date in EDC, since per PPD Lab the collection date is updated as 21AUG2020.Thanks' (Site from DM).		23 Mar 2021 09:47:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19AUG2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Mar 2021 10:45:31
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19AUG2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'sample collected and in edc' (Site from DM).		10 Mar 2021 22:33:36
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19AUG2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).		08 Mar 2021 08:35:47

**US3462076**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:51:48**

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020'	(b) (4), (b) (6)	24 Feb 2021 17:47:14

**US3462076**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:51:48**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
User accepted default value 'Day 5 (Day 5)'		24 Feb 2021 17:51:25



**US3462076**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:51:48**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:33:10
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:51:25

**US3462076**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:51:48**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:33:10
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:51:25

**US3462076**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:51:48**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
User accepted default value 'Day 7 (Day 7)'		24 Feb 2021 17:51:25

**US3462076**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:51:48**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:33:10
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:51:25

**US3462076**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:51:48**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:33:10
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:51:25

**US3462076**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:51:48**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
User accepted default value 'Day 9 (Day 9)'		24 Feb 2021 17:51:25

**US3462076**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:51:48**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:33:10
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:51:25

**US3462076**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:51:48**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:33:10
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:51:25



**US3462076**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 22:51:48**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
User accepted default value 'Day 14 (Day 14)'		24 Feb 2021 17:51:25

**US3462076**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 22:51:48**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:33:10
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:51:25

**US3462076**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 22:51:48**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:33:10
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:51:25

**US3462076**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:51:48**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
User accepted default value 'Day 21 (Day 21)'		24 Feb 2021 17:51:25

**US3462076**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:51:48**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:33:10
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:51:25

**US3462076**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:51:48**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:33:10
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:51:25

**US3462076**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 22:51:48**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
User accepted default value 'Day 28 (Day 28)'		24 Feb 2021 17:51:25

**US3462076**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 22:51:48**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:33:10
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:51:25



**US3462076**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 22:51:48**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:33:10
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:51:25

**US3462076**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:51:48**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:08:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:44:40

**US3462076**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:51:48**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:08:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:44:40

**US3462076**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:51:48**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:08:12
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:44:40

**US3462076**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:51:48**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
User entered 'SICKD1'	System	24 Feb 2021 17:44:40

**US3462076**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:31:55
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:45:51

**US3462076**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:31:55
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:45:51

**US3462076**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:31:55
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered '09:00'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:45:51



**US3462076**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
User entered '17 Aug 2020 09:00'	System	24 Feb 2021 17:45:51

**US3462076**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:31:55
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered '169.6' cm	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:45:51
DataPoint set to visible.	System	24 Feb 2021 17:44:40

US3462076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:31:55
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered '76.3' kg	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:45:51
DataPoint set to visible.	System	24 Feb 2021 17:44:40

**US3462076**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:31:55
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:45:51

**US3462076**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:31:55
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:45:51

**US3462076**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:31:55
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:45:51

**US3462076**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:31:55
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered '90'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:45:51

**US3462076**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
User entered 'bpm'	System	24 Feb 2021 17:45:51



**US3462076**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:31:55
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered '16'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:45:51

**US3462076**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
User entered 'breaths/min'	System	24 Feb 2021 17:45:51

**US3462076**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:31:55
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered '108'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:45:51

**US3462076**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
User entered 'mmHg'	System	24 Feb 2021 17:45:51

**US3462076**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:31:55
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered '72'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:45:51

US3462076

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:51:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
User entered 'mmHg'	System	24 Feb 2021 17:45:51

**US3462076**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50

**US3462076**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:51:48**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50



**US3462076**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:51:48**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:32:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:46:08

**US3462076**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:51:48**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:32:02
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:46:08

US3462076

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:51:48

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:32:11
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:46:21

**US3462076**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 22:51:48**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:43:50
DataPoint Verified.		20 Apr 2021 22:32:11
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:46:21

US3462076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Jan 2021 22:15:14

US3462076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:48

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 22:15:14

US3462076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:51:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 22:15:14

**US3462076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:51:48**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User entered 'UNBLND_DECIDE'	System	23 Jan 2021 22:15:14



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:51:48

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 22:15:28

**US3462076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:51:48**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:22:06

**US3462076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:51:48**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Jan 2021 22:15:28

**US3462076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:51:48**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:22:06

US3462076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:51:48

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 22:15:28

US3462076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:51:48

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	23 Jan 2021 22:15:28

US3462076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:51:48

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	23 Jan 2021 22:15:28

US3462076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:51:48

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 22:15:28



US3462076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:51:48

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'No (N)'	(b) (4), (b) (6)	23 Jan 2021 22:15:28

**US3462076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:51:48**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User entered empty.	System	23 Jan 2021 22:15:28

**US3462076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:51:48**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User entered empty.	System	23 Jan 2021 22:15:28

US3462076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 22:15:37

US3462076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 22:15:37

US3462076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:51:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '14:13'	(b) (4), (b) (6)	23 Jan 2021 22:15:37

**US3462076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:51:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User entered '12 Jan 2021 14:13'	System	23 Jan 2021 22:15:37

US3462076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:51:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 22:15:50



US3462076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:51:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '12 Jan 2021'	(b) (4), (b) (6)	23 Jan 2021 22:15:50

US3462076

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:51:48

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '14:02'	(b) (4), (b) (6)	23 Jan 2021 22:15:50

**US3462076**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:51:48**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:52:09
User entered '12 Jan 2021 14:02'	System	23 Jan 2021 22:15:50

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 11 Aug 2021 22:51:48**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:08:01
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:12
User entered 'Yes (Y)'	Savannah Peterson (b) (4) (b) (4)	08 Sep 2020 23:16:50

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:51:48**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03

US3462076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User coded data point as SOC: Injury, poisoning and procedural complications, HLT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Ligament sprain, LLT: Wrist sprain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 21:24:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 21:24:31
Data point term sent to Coder	System	05 Nov 2020 21:23:47
User entered 'right wrist sprain'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:23:13

US3462076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	05 Nov 2020 21:23:13

US3462076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered 'No (N)'	Savannah Peterson (b) (4)	05 Nov 2020 21:23:13



US3462076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered 'No (N)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:23:13

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:51:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered '07 Sep 2020'	Savannah Peterson (b) (4)	05 Nov 2020 21:23:13

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:51:48**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 21:23:13

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:51:48**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User entered empty.	System	05 Nov 2020 21:23:13

US3462076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered 'No (N)'	Savannah Peterson (b) (4)	05 Nov 2020 21:23:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered '22 Sep 2020'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:23:13

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:51:48**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 21:23:13

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:51:48**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User entered empty.	System	05 Nov 2020 21:23:13



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:48

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered 'Grade 3/Severe (Grade 3/Severe)'	Savannah Peterson (b) (4)	05 Nov 2020 21:23:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered 'No (N)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:23:13

US3462076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:48

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered '0'	Savannah Peterson (b) (4)	05 Nov 2020 21:23:13

US3462076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:48

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered '0'	Savannah Peterson (b) (4)	05 Nov 2020 21:23:13

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:51:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered '0'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:23:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 21:23:13

US3462076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:48

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 21:23:13

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:51:48**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 21:23:13



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:51:48**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 21:23:13

US3462076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered '0'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:23:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered '0'	Savannah Peterson (b) (4)	05 Nov 2020 21:23:13

US3462076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:48

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered '0'	Savannah Peterson (b) (4)	05 Nov 2020 21:23:13

US3462076

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 21:23:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 21:23:38
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Savannah Peterson (b) (4)	05 Nov 2020 21:23:38
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 21:23:13
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 21:23:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 21:23:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 21:23:38
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Savannah Peterson (b) (4)	05 Nov 2020 21:23:38
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 21:23:13
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 21:23:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:48

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 21:23:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 21:23:38
User entered 'None (NONE)' reason for change: Data Entry Error	Savannah Peterson (b) (4)	05 Nov 2020 21:23:38
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 21:23:13
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 21:23:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:48

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered 'l'	Savannah Peterson (b) (4)	05 Nov 2020 21:23:13



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:51:48**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered '0'	Savannah Peterson (b) (4)	05 Nov 2020 21:23:13

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:51:48**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered '0'	Savannah Peterson (b) (4)	05 Nov 2020 21:23:13

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:51:48

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Savannah Peterson (b) (4)	05 Nov 2020 21:23:13

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:51:48**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered empty.	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:23:13

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:51:48**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 21:23:13

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:51:48**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User entered '0'	System	05 Nov 2020 21:23:13

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:51:48**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03
User entered 'I'	System	05 Nov 2020 21:23:13

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:51:48**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:03



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:51:48**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:51:48

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User closed query 'Per MM: Please update AE to provide symptoms.' (Site from DM).	(b) (4)	26 Feb 2021 15:07:29
Query 'Per MM: Please update AE to provide symptoms.' answered with 'per source document no symptoms where reported in source doc' (Site from DM).	(b) (4), (b) (6)	
DataPoint Verified.		
User opened query 'Per MM: Please update AE to provide symptoms.' (Site from DM).		
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory tract infection - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 21:29:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	05 Nov 2020 21:29:17
Data point term sent to Coder	System	05 Nov 2020 21:28:03
User entered 'upper respiratory tract infection'	Savannah Peterson (b) (4)	05 Nov 2020 21:27:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:51:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered 'No (N)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:27:28

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:51:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered 'No (N)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:27:28

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:51:48**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered 'No (N)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:27:28

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:51:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered '15 Aug 2020'	Savannah Peterson (b) (4)	05 Nov 2020 21:27:28

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:51:48**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 21:27:28

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:51:48**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User entered empty.	System	05 Nov 2020 21:27:28



**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:51:48**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered 'No (N)'	Savannah Peterson (b) (4)	05 Nov 2020 21:27:28

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:51:48**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered '21 Aug 2020'	Savannah Peterson (b) (4)	05 Nov 2020 21:27:28

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:51:48**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 21:27:28

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:51:48**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User entered empty.	System	05 Nov 2020 21:27:28

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:51:48

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Savannah Peterson (b) (4)	05 Nov 2020 21:27:28

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Folder: Adverse Events

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Generated On: 11 Aug 2021 22:51:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered 'No (N)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:27:28

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:51:48**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered '0'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:27:28

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:51:48**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered '0'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:27:28



**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:51:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered '0'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:27:28

US3462076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:51:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 21:27:28

US3462076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:51:48

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 21:27:28

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:51:48**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 21:27:28

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:51:48**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 21:27:28

US3462076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:51:48

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered '0'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:27:28

US3462076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:51:48

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered '0'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:27:28

US3462076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:51:48

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered '0'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:27:28



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:51:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered 'Not Related (NOT RELATED)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:27:28

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:51:48**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered 'Not Related (NOT RELATED)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:27:28

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:51:48**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered 'None (NONE)'	Savannah Peterson (b) (4)	05 Nov 2020 21:27:28

US3462076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:51:48

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered '0'	Savannah Peterson (b) (4)	05 Nov 2020 21:27:28

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:51:48**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered 'l'	Savannah Peterson (b) (4)	05 Nov 2020 21:27:28

US3462076

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:51:48

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered '0'	Savannah Peterson (b) (4)	05 Nov 2020 21:27:28

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:51:48**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Savannah Peterson (b) (4)	05 Nov 2020 21:27:28

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:51:48**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered empty.	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:27:28



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:51:48**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 21:27:28

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:51:48**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User entered '0'	System	05 Nov 2020 21:27:28

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:51:48**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32
User entered '0'	System	05 Nov 2020 21:27:28

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:51:48**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:24:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:48

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Dec 2020 00:34:09
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 21:58:31
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 21:58:31
	(b) (4)	
Data point term sent to Coder	System	05 Nov 2020 21:42:47
User entered 'nausea'	Savannah Peterson (b) (4)	05 Nov 2020 21:42:36
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:51:48**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered 'No (N)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:42:36

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 21:43:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 21:43:01
User entered 'No (N)' reason for change: Data Entry Error	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:43:01
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 21:42:36
User entered empty.	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:42:36

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered 'No (N)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:42:36



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered '25 Sep 2020'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:42:36

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:51:48**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered empty.	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:42:36

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:51:48**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 21:42:36

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:07:36
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' answered with 'has not yet resolved as subject is still pregnant' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 17:27:20
DataPoint Verified.		17 Dec 2020 00:34:09
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).		29 Nov 2020 09:42:27
User entered 'Yes (Y)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:42:36

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered empty.	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:42:36

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:51:48**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered empty.	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:42:36

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:51:48**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 21:42:36

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:51:48**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered 'Grade 1/Mild (Grade 1/Mild)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:42:36



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered 'No (N)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:42:36

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:51:48**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered '0'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:42:36

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:51:48**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered '0'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:42:36

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:51:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered '0'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:42:36

US3462076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:48

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered empty.	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:42:36

US3462076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:48

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered empty.	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:42:36

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:51:48**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered empty.	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:42:36

US3462076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:48

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered empty.	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:42:36



**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:51:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered '0'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:42:36

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:51:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered '0'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:42:36

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:51:48**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered '0'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:42:36

US3462076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered 'Not Related (NOT RELATED)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:42:36

US3462076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:48

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered 'Not Related (NOT RELATED)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:42:36

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:51:48**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered 'None (NONE)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:42:36

US3462076

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:51:48

None

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	05 Nov 2020 21:43:01
User entered '0' reason for change: Data Entry Error	Savannah Peterson (b) (4)	05 Nov 2020 21:43:01
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4) System	05 Nov 2020 21:42:36
User entered '1'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:42:36

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:51:48**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered 'I'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:42:36



**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:51:48**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered '0'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:42:36

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:51:48**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:42:36

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:51:48**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered empty.	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:42:36

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:51:48**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:05:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:34:09
User entered empty.	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:42:36

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:51:48**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 21:42:36

**US3462076**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:51:48**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 21:42:36

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:51:48

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:08:01
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:20:53

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Luck singer (b) (4)	06 Apr 2021 14:33:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTS YNonym: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 12:27:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 12:27:45
Data point term sent to Coder	System	10 Sep 2020 23:22:16
User entered 'WOMENS COMPLETE VITAMIN'	(b) (4), (b) (6)	10 Sep 2020 23:21:28



US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Oct 2020 18:36:53
User entered 'No (N)'		10 Sep 2020 23:21:28

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'SUPPLEMENT'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:21:28

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered '1'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:21:28

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:21:28

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:21:28

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:21:28

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:21:28

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:21:28



US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:21:28

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'UN May 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:21:28

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:21:28

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:21:28

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:21:28

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:51:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:21:28

**US3462076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:51:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 23:21:28

**US3462076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:51:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 23:21:28



**US3462076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:51:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 23:21:28

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 23:22:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 23:22:52
Data point term sent to Coder	System	10 Sep 2020 23:22:14
User entered 'TYLENOL'	(b) (4), (b) (6)	10 Sep 2020 23:22:05

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User closed query 'Per DM CLR: Prophylaxis= YES. Please review if this should to 'NO' as there is an ongoing MH that corresponds to this indication.Please update response as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 11:13:04
Query 'Per DM CLR: Prophylaxis= YES. Please review if this should to 'NO' as there is an ongoing MH that corresponds to this indication.Please update response as appropriate.' answered with 'UPDATED' (Site from DM).		09 Oct 2020 18:37:15
User entered 'No (N)' reason for change: Data Entry Error		09 Oct 2020 18:37:06
User opened query 'Per DM CLR: Prophylaxis= YES. Please review if this should to 'NO' as there is an ongoing MH that corresponds to this indication.Please update response as appropriate.' (Site from DM).		03 Oct 2020 11:47:42
User entered 'Yes (Y)'		10 Sep 2020 23:22:05

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'OCCASIONAL BODY PAIN'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:22:05

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 500 MG, 1000 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 14:15:18
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 500 MG, 1000 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:20:20
User entered '325' reason for change: Data Entry Error	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:19:52
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 500 MG, 1000 MG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 11:47:37
User entered '1'		10 Sep 2020 23:22:05

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User closed query 'Per DM CLR: Note that this is not the expected unit for this medication. Please update the unit as appropriate (i.e. mg) or provide explanation for alternate unit.' (Site from DM).	(b) (4)	26 Feb 2021 15:06:47
Query 'Per DM CLR: Note that this is not the expected unit for this medication. Please update the unit as appropriate (i.e. mg) or provide explanation for alternate unit.' answered with 'updated Data' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 17:14:24
User entered 'mg (mg)' reason for change: Data Entry Error		24 Feb 2021 17:14:15
User opened query 'Per DM CLR: Note that this is not the expected unit for this medication. Please update the unit as appropriate (i.e. mg) or provide explanation for alternate unit.' (Site from DM).		23 Nov 2020 08:27:56
User entered 'tablet (TABLET)'		10 Sep 2020 23:22:05

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:22:05

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:22:05



US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:22:05

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:48

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:22:05

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:22:05

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'UN Jan 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:22:05

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:22:05

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:22:05

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:22:05

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:51:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:22:05



**US3462076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:51:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 23:22:05

US3462076

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:51:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 23:22:05

**US3462076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:51:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 23:22:05

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Luckinger (b) (4)	06 Apr 2021 14:33:22
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS, PRODUCT: ETONOGESTREL, PRODUCTSYNONYM: NEXPLANON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 22:46:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 22:46:35
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	05 Apr 2021 22:46:06 05 Apr 2021 22:45:12
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS, PRODUCT: ETONOGESTREL, PRODUCTSYNONYM: NEXPLANON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 10:08:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 10:08:35
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	24 Feb 2021 17:15:05 24 Feb 2021 17:14:59
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS, PRODUCT: ETONOGESTREL, PRODUCTSYNONYM: NEXPLANON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 21:22:24

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:48

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4) System Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:22:24  05 Nov 2020 21:21:34 05 Nov 2020 21:21:16
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS, PRODUCT: ETONOGESTREL, PRODUCTSYNONYM: NEXPLANON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 08:25:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'NEXPLANON IMPLANT'	Coder Import (b) (4) (b) (4) System (b) (4), (b) (6)  (b) (4)	11 Sep 2020 08:25:47  10 Sep 2020 23:25:21 10 Sep 2020 23:24:31

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:24:31

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'BIRTH CONTROL'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:24:31

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered '1'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:24:31



US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:24:31

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'IMPLANT'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:24:31

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:24:31

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'EVERY 4 YEARS'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:24:31

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:48

[Route of administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as Intramuscular. Please update route as appropriate. Else, clarify. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	06 Apr 2021 14:33:40
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as Intramuscular. Please update route as appropriate. Else, clarify. ' answered with 'Data Updated' (Site from DM). User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as Intramuscular. Please update route as appropriate. Else, clarify. ' (Site from DM). User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM). Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'updated' (Site from DM). User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Data Entry Error	Gregg Lucksinger (b) (4) (b) (4) (b) (4), (b) (6)	06 Apr 2021 14:33:22 05 Apr 2021 22:45:31 05 Apr 2021 22:45:12 11 Mar 2021 09:53:18 26 Feb 2021 15:06:52 24 Feb 2021 17:17:31 24 Feb 2021 17:14:59
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).		06 Jan 2021 15:55:03
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Savannah Peterson (b) (4)	05 Nov 2020 21:21:16
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:24:31

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User closed query 'Per CDM: 'Route of Administration' is 'Other' and 'If route of administration is Other, specify' is entered as 'Subdermally'. Please review predefined options available for 'Route of Administration' and confirm or update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 14:15:26
Query 'Per CDM: 'Route of Administration' is 'Other' and 'If route of administration is Other, specify' is entered as 'Subdermally'. Please review predefined options available for 'Route of Administration' and confirm or update as appropriate.' answered with 'updated' (Site from DM).	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:21:24
User entered empty; reason for change Data Entry Error	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:21:16
User opened query 'Per CDM: 'Route of Administration' is 'Other' and 'If route of administration is Other, specify' is entered as 'Subdermally'. Please review predefined options available for 'Route of Administration' and confirm or update as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 10:45:39
User entered 'SUBDERMALLY'	(b) (4), (b) (6)	10 Sep 2020 23:24:31

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'UN Aug 2019'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:24:31

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 23:24:31



US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User closed query 'Per DM CLR: Please review response to Ongoing? = NO, as the effect of this medication is not expected to end in the recorded timeframe. Otherwise, clarify.' (Site from DM).	(b) (4)	26 Feb 2021 15:06:54
Query 'Per DM CLR: Please review response to Ongoing? = NO, as the effect of this medication is not expected to end in the recorded timeframe. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 17:17:41
User entered 'Yes (Y)' reason for change: Data Entry Error		24 Feb 2021 17:15:23
User opened query 'Per DM CLR: Please review response to Ongoing? = NO, as the effect of this medication is not expected to end in the recorded timeframe. Otherwise, clarify.' (Site from DM).		06 Jan 2021 15:55:26
User entered 'No (N)'		10 Sep 2020 23:24:31

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:15:23
User entered 'UN Aug 2020'		10 Sep 2020 23:24:31

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:51:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 23:24:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 23:24:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 23:24:39
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 23:24:31
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 23:24:31

**US3462076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:51:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 23:24:31

**US3462076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:51:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 23:24:31

**US3462076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:51:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 23:24:31

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:17
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 21:17:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 21:17:28
Data point term sent to Coder	System	05 Nov 2020 21:16:17
User entered 'acetaminophen'	Savannah Peterson (b) (4)	05 Nov 2020 21:15:29

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:17
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'No (N)'	Savannah Peterson (b) (4)	05 Nov 2020 21:15:29



US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:17
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'upper respiratory tract infection'	Savannah Peterson (b) (4)	05 Nov 2020 21:15:29

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:17
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered '500'	Savannah Peterson (b) (4)	05 Nov 2020 21:15:29

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:17
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'mg (mg)'	Savannah Peterson (b) (4)	05 Nov 2020 21:15:29

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:17
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 21:15:29

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:17
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'twice daily (BID)'	Savannah Peterson (b) (4)	05 Nov 2020 21:15:29

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:17
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 21:15:29

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:17
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'Oral (ORAL)'	Savannah Peterson (b) (4)	05 Nov 2020 21:15:29

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:17
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 21:15:29



US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:17
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered '17 Aug 2020'	Savannah Peterson (b) (4)	05 Nov 2020 21:15:29

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:17
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered '0'	Savannah Peterson (b) (4)	05 Nov 2020 21:15:29

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:17
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'No (N)'	Savannah Peterson (b) (4)	05 Nov 2020 21:15:29

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:17
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered '18 Aug 2020'	(b) (4) Savannah Peterson (b) (4)	05 Nov 2020 21:15:29

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:17
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'No (N)'	Savannah Peterson (b) (4)	05 Nov 2020 21:15:29

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:48

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:17
User entered '2'	System	05 Nov 2020 21:15:29

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:51:48

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:17
User entered '1'	System	05 Nov 2020 21:15:29

**US3462076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:51:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:17
User entered '804 (804)'	System	05 Nov 2020 21:15:29



US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:22
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS, PRODUCT: NORETHISTERONE, PRODUCTSYNONYM: TULANA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 05:38:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	06 Nov 2020 05:38:29
Data point term sent to Coder	System	05 Nov 2020 21:17:21
User entered 'tulana'	Savannah Peterson (b) (4)	05 Nov 2020 21:16:56
	(b) (4)	

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:22
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	05 Nov 2020 21:16:56

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:22
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'birth control'	Savannah Peterson (b) (4)	05 Nov 2020 21:16:56

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:22
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:07:06
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'Per Source document data is correct ' (Site from DM).		24 Feb 2021 17:32:02
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).		06 Jan 2021 15:56:02
User entered '0.3'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:16:56

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:22
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'mg (mg)'	Savannah Peterson (b) (4)	05 Nov 2020 21:16:56

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:22
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 21:16:56

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:22
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'once daily (QD)'	Savannah Peterson (b) (4)	05 Nov 2020 21:16:56

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:22
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 21:16:56



US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:22
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'Oral (ORAL)'	Savannah Peterson (b) (4)	05 Nov 2020 21:16:56

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:22
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 21:16:56

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:22
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered '16 Aug 2020'	Savannah Peterson (b) (4)	05 Nov 2020 21:16:56

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:22
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered '0'	Savannah Peterson (b) (4)	05 Nov 2020 21:16:56

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:22
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'No (N)'	Savannah Peterson (b) (4)	05 Nov 2020 21:16:56

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:22
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered '07 Sep 2020'	(b) (4) Savannah Peterson (b) (4)	05 Nov 2020 21:16:56

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:22
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'No (N)'	Savannah Peterson (b) (4)	05 Nov 2020 21:16:56

**US3462076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:51:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:22
User entered '1'	System	05 Nov 2020 21:16:56



**US3462076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:51:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:22
User entered '1'	System	05 Nov 2020 21:16:56

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:51:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:13:22
User entered '804 (804)'	System	05 Nov 2020 21:16:56

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 07:13:42
Data hard locked.		01 May 2021 07:13:26
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Nov 2020 21:19:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 21:19:29
Data point term sent to Coder	System	05 Nov 2020 21:18:24
User entered 'ondansetron'	Savannah Peterson (b) (4) (b) (4)	05 Nov 2020 21:18:03

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 07:13:42
Data hard locked.		01 May 2021 07:13:26
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'No (N)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:18:03
	(b) (4)	

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:48

[Indication](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 07:13:42
Data hard locked.		01 May 2021 07:13:26
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'nausea'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:18:03
	(b) (4)	

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 07:13:42
Data hard locked.		01 May 2021 07:13:26
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered '4'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:18:03
	(b) (4)	

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 07:13:42
Data hard locked.		01 May 2021 07:13:26
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'mg (mg)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:18:03
	(b) (4)	

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 07:13:42
Data hard locked.		01 May 2021 07:13:26
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered empty.	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:18:03
	(b) (4)	



US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 07:13:42
Data hard locked.		01 May 2021 07:13:26
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'as needed (PRN)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:18:03
	(b) (4)	

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:48

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 07:13:42
Data hard locked.		01 May 2021 07:13:26
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered empty.	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:18:03
	(b) (4)	

**US3462076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:51:48**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 07:13:42
Data hard locked.		01 May 2021 07:13:26
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'Oral (ORAL)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:18:03
	(b) (4)	

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 07:13:42
Data hard locked.		01 May 2021 07:13:26
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered empty.	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:18:03
	(b) (4)	

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 07:13:42
Data hard locked.		01 May 2021 07:13:26
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered '02 Oct 2020'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:18:03
	(b) (4)	

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 07:13:42
Data hard locked.		01 May 2021 07:13:26
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered '0'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:18:03
	(b) (4)	

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 07:13:42
Data hard locked.		01 May 2021 07:13:26
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'Yes (Y)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:18:03
	(b) (4)	

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 07:13:42
Data hard locked.		01 May 2021 07:13:26
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered empty.	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:18:03
	(b) (4)	



US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 07:13:42
Data hard locked.		01 May 2021 07:13:26
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'No (N)'	(b) (4)	
	Savannah Peterson (b) (4)	05 Nov 2020 21:18:03
	(b) (4)	

**US3462076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:51:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 07:13:42
Data hard locked.		01 May 2021 07:13:26
User entered empty.	System	05 Nov 2020 21:18:03

**US3462076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:51:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 07:13:42
Data hard locked.		01 May 2021 07:13:26
User entered empty.	System	05 Nov 2020 21:18:03

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:51:48

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 07:13:42
Data hard locked.		01 May 2021 07:13:26
User entered empty.	System	05 Nov 2020 21:18:03

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:48

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:16
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 21:20:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 21:20:38
Data point term sent to Coder	System	05 Nov 2020 21:19:28
User entered 'tylenol'	Savannah Peterson (b) (4)	05 Nov 2020 21:19:10

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:48

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:16
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'No (N)'	Savannah Peterson (b) (4)	05 Nov 2020 21:19:10

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:48

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:16
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:07:11
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' answered with 'Does Not Meet AE Reporting Criteria' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 17:32:41





US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:48

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:16
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered '325'	Savannah Peterson (b) (4)	05 Nov 2020 21:19:10

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:48

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:16
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'mg (mg)'	Savannah Peterson (b) (4)	05 Nov 2020 21:19:10

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:48

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:16
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 21:19:10

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:48

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:16
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'as needed (PRN)'	Savannah Peterson (b) (4)	05 Nov 2020 21:19:10

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:48

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:16
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 21:19:10

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:48

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:16
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'Oral (ORAL)'	Savannah Peterson (b) (4)	05 Nov 2020 21:19:10

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:48

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:16
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered empty.	Savannah Peterson (b) (4)	05 Nov 2020 21:19:10

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:16
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered '04 Sep 2020'	Savannah Peterson (b) (4)	05 Nov 2020 21:19:10



US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:48

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:16
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered '0'	Savannah Peterson (b) (4)	05 Nov 2020 21:19:10

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:48

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:16
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'No (N)'	Savannah Peterson (b) (4)	05 Nov 2020 21:19:10

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:48

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:16
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered '06 Sep 2020'	(b) (4) Savannah Peterson (b) (4)	05 Nov 2020 21:19:10
	(b) (4)	

US3462076

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:51:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:16
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:33:22
User entered 'Yes (Y)'	Savannah Peterson (b) (4)	05 Nov 2020 21:19:10

**US3462076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:51:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:16
User entered empty.	System	05 Nov 2020 21:19:10

**US3462076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:51:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:16
User entered empty.	System	05 Nov 2020 21:19:10

**US3462076**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:51:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:14:16
User entered empty.	System	05 Nov 2020 21:19:10

US3462076

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 22:51:48**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
	(b) (4)	
User entered 'No (N)'	Savannah Peterson (b) (4)	05 Nov 2020 22:15:02
	(b) (4)	



**US3462076**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:51:48**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Reviewed for Safety.		09 Sep 2020 17:58:13
User entered 'USA-US093-2020-MRNA-1273-P301000002'	System	09 Sep 2020 17:57:35

US3462076

Folder: SAE USA-US093-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Un-reviewed for Safety.	System	08 Nov 2020 02:14:06
User entered 'No (N)'	System	08 Nov 2020 02:14:06
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:58:13
User entered 'Yes (Y)'	System	09 Sep 2020 17:57:35

**US3462076**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:51:48**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Reviewed for Safety.		09 Sep 2020 17:58:13
User entered 'No (N)'	System	09 Sep 2020 17:57:35

**US3462076**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:51:48**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	17 Dec 2020 00:33:01
Reviewed for Safety.		09 Sep 2020 17:58:13
User entered 'No (N)'	System	09 Sep 2020 17:57:35

**US3462076**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:51:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Reviewed for Safety.		09 Sep 2020 17:58:13
User entered 'No (N)'	System	09 Sep 2020 17:57:35

**US3462076**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:51:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	17 Dec 2020 00:33:01
Reviewed for Safety.		09 Sep 2020 17:58:13
User entered 'No (N)'	System	09 Sep 2020 17:57:35

**US3462076**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:51:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	17 Dec 2020 00:33:01
Reviewed for Safety.		09 Sep 2020 17:58:13
User entered 'No (N)'	System	09 Sep 2020 17:57:35

US3462076

Folder: SAE USA-US093-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Un-reviewed for Safety.	System	08 Nov 2020 02:14:06
User entered 'No (N)'	System	08 Nov 2020 02:14:06
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:58:13
User entered 'Yes (Y)'	System	09 Sep 2020 17:57:35



**US3462076**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:51:48**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Reviewed for Safety.		06 Nov 2020 20:04:00
Amendment Manager: User entered 'Edward'	System	14 Sep 2020 21:46:22

**US3462076**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:51:48**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Reviewed for Safety.		06 Nov 2020 20:04:00
Amendment Manager: User entered 'Kerwin'	System	14 Sep 2020 21:46:22

**US3462076**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:51:48**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Reviewed for Safety.		06 Nov 2020 20:04:00
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:25:52
User entered 'US' (non-conformant).	System	09 Sep 2020 17:58:19

US3462076

Folder: SAE USA-US093-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '2'	(b) (4)	06 Nov 2020 20:04:24
User entered '1'	System	09 Sep 2020 17:58:19

**US3462076**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:51:48**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Reviewed for Safety.		09 Sep 2020 17:58:13
User entered 'USA-US093-2020-MRNA-1273-P301000002'	System	09 Sep 2020 17:57:35

US3462076

Folder: SAE USA-US093-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Un-reviewed for Safety.	System	08 Nov 2020 02:14:06
User entered 'No (N)'	System	08 Nov 2020 02:14:06
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:58:13
User entered 'Yes (Y)'	System	09 Sep 2020 17:57:35

**US3462076**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:51:48**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	17 Dec 2020 00:33:01
Reviewed for Safety.		09 Sep 2020 17:58:13
User entered 'No (N)'	System	09 Sep 2020 17:57:35

**US3462076**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:51:48**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Reviewed for Safety.		09 Sep 2020 17:58:13
User entered 'No (N)'	System	09 Sep 2020 17:57:35



**US3462076**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:51:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Reviewed for Safety.		09 Sep 2020 17:58:13
User entered 'No (N)'	System	09 Sep 2020 17:57:35

**US3462076**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:51:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Reviewed for Safety.		09 Sep 2020 17:58:13
User entered 'No (N)'	System	09 Sep 2020 17:57:35

**US3462076**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:51:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Reviewed for Safety.		09 Sep 2020 17:58:13
User entered 'No (N)'	System	09 Sep 2020 17:57:35

US3462076

Folder: SAE USA-US093-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Un-reviewed for Safety.	System	08 Nov 2020 02:14:06
User entered 'No (N)'	System	08 Nov 2020 02:14:06
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:58:13
User entered 'Yes (Y)'	System	09 Sep 2020 17:57:35

**US3462076**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:51:48**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Reviewed for Safety.		06 Nov 2020 20:04:00
Amendment Manager: User entered 'Edward'	System	14 Sep 2020 21:46:22

**US3462076**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:51:48**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Reviewed for Safety.		06 Nov 2020 20:04:00
Amendment Manager: User entered 'Kerwin'	System	14 Sep 2020 21:46:22

**US3462076**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:51:48**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Reviewed for Safety.		06 Nov 2020 20:04:00
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:25:52
User entered 'US' (non-conformant).	System	09 Sep 2020 17:58:19

US3462076

Folder: SAE USA-US093-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
User entered '2'	(b) (4)	06 Nov 2020 20:04:24
User entered '1'	System	09 Sep 2020 17:58:19



**US3462076**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (1)**

**Generated On: 11 Aug 2021 22:51:48**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
User entered '09/Sep/2020 13:58'	System	09 Sep 2020 17:58:19

US3462076

Folder: SAE USA-US093-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:51:48

**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.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Reviewed for Safety.		06 Nov 2020 20:04:00
User entered '1'		09 Sep 2020 17:58:19

**US3462076**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:51:48**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Reviewed for Safety.		09 Sep 2020 17:58:13
User entered 'USA-US093-2020-MRNA-1273-P301000002'	System	09 Sep 2020 17:57:35

US3462076

Folder: SAE USA-US093-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:48

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Un-reviewed for Safety.	System	08 Nov 2020 02:14:06
User entered 'No (N)'	System	08 Nov 2020 02:14:06
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:58:13
User entered 'Yes (Y)'	System	09 Sep 2020 17:57:35

**US3462076**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:51:48**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Reviewed for Safety.		09 Sep 2020 17:58:13
User entered 'No (N)'	System	09 Sep 2020 17:57:35

**US3462076**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:51:48**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Reviewed for Safety.		09 Sep 2020 17:58:13
User entered 'No (N)'	System	09 Sep 2020 17:57:35

**US3462076**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:51:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Reviewed for Safety.		09 Sep 2020 17:58:13
User entered 'No (N)'	System	09 Sep 2020 17:57:35

**US3462076**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:51:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Reviewed for Safety.		09 Sep 2020 17:58:13
User entered 'No (N)'	System	09 Sep 2020 17:57:35



**US3462076**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:51:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Reviewed for Safety.		09 Sep 2020 17:58:13
User entered 'No (N)'	System	09 Sep 2020 17:57:35

US3462076

Folder: SAE USA-US093-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:48

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Un-reviewed for Safety.	System	08 Nov 2020 02:14:06
User entered 'No (N)'	System	08 Nov 2020 02:14:06
Reviewed for Safety.	(b) (4), (b) (6)	09 Sep 2020 17:58:13
User entered 'Yes (Y)'	System	09 Sep 2020 17:57:35

**US3462076**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:51:48**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Reviewed for Safety.		06 Nov 2020 20:04:00
Amendment Manager: User entered 'Edward'	System	14 Sep 2020 21:46:22

**US3462076**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:51:48**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Reviewed for Safety.		06 Nov 2020 20:04:00
Amendment Manager: User entered 'Kerwin'	System	14 Sep 2020 21:46:22

**US3462076**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:51:48**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
Reviewed for Safety.		06 Nov 2020 20:04:00
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 04:25:52
User entered 'US' (non-conformant).	System	09 Sep 2020 17:58:19

US3462076

Folder: SAE USA-US093-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:51:48

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
	(b) (4)	
User entered '2'	System	06 Nov 2020 20:04:24
User entered '1'	System	09 Sep 2020 17:58:19

**US3462076**

**Folder: SAE USA-US093-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (2)**

**Generated On: 11 Aug 2021 22:51:48**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
User entered '06/Nov/2020 20:04'	System	06 Nov 2020 20:04:24

US3462076

Folder: SAE USA-US093-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:51:48

**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.	Gregg Lucksinger (b) (4)	19 Feb 2021 19:39:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 00:33:01
User entered 'I'		06 Nov 2020 20:04:24