

US3462374 (Prod: Crisor, LLC)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:43:38

All time stamps listed in this document are displayed in GMT

US3462374

**Form: Participant Creation**

**Data signed:** (b) (4) 19 Feb 2021 20:40:26

**Generated On:** 11 Aug 2021 22:43:38

---

[Participant ID](#)

US3462374

---

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

---

---

US3462374

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:00:08

Generated On: 11 Aug 2021 22:43:38

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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

---

US3462374

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 02:00:08

Generated On: 11 Aug 2021 22:43:38

Date of Birth (MMM yyyy)	(b) (6) 1981
Age	39
Age Units	YEARS
Age (Derived)	39
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

US3462374

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 02:00:08

Generated On: 11 Aug 2021 22:43:38

Date of Informed Consent (*dd MMM yyyy*) 27 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes   
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

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

Was this participant screened previously? Yes   
No

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

Enrollment Trigger 1

US3462374

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 02:00:08

Generated On: 11 Aug 2021 22:43:38

---

Did the participant meet all eligibility criteria?

Yes

No

---

US3462374

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 02:00:08

Generated On: 11 Aug 2021 22:43:38

---

Were any significant conditions reported?

Yes

No

---

US3462374

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 02:00:08

Generated On: 11 Aug 2021 22:43:38

Condition	SEASONAL AND PERENNIAL ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3462374

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 02:00:08

Generated On: 11 Aug 2021 22:43:38

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

US3462374

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 02:00:08

Generated On: 11 Aug 2021 22:43:38

Condition	MILD DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3462374

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 02:00:08

Generated On: 11 Aug 2021 22:43:38

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

US3462374

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 02:00:08

Generated On: 11 Aug 2021 22:43:38

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

US3462374

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:00:08

Generated On: 11 Aug 2021 22:43:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	27 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	14:36 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 14:36
Height ( <i>xxx.x</i> )	191 cm
Weight ( <i>xxx.x</i> )	81 kg
BMI ( <i>xxx.x</i> )	22.20334 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3462374

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:00:08

Generated On: 11 Aug 2021 22:43:38

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

27 AUG 2020

---

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

---

US3462374

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:00:08

Generated On: 11 Aug 2021 22:43:38

---

**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

---

**Specify**

---

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

**No Risk Identified** False

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

US3462374

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:00:08

Generated On: 11 Aug 2021 22:43:38

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

US3462374

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:00:14

Generated On: 11 Aug 2021 22:43:38

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 27 AUG 2020

---

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

---

Folder OID VISIT1

---

US3462374

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 02:00:14

Generated On: 11 Aug 2021 22:43:38

What was the date of randomization? (dd MMM yyyy) 27 AUG 2020

What was the participant's randomization number? 109434

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

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

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

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

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

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

Liver Disease Yes  No

Human Immunodeficiency Virus (HIV) infection Yes  No

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 02:00:14

Generated On: 11 Aug 2021 22:43:38

---

Height	ND - Not Done
Weight	ND - Not Done

---

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:00:14

Generated On: 11 Aug 2021 22:43:38

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 ( <i>dd MMM yyyy</i> )	27 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	14:36 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 14:36
Temperature ( <i>xxx.x</i> )	99.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse ( <i>xxx</i> )	64 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	68 mmHg
Diastolic Blood Pressure units	MMHG

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:00:14

Generated On: 11 Aug 2021 22:43:38

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	27 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	17:42 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 17:42
Temperature ( <i>xxx.x</i> )	98.9 F
Route of measurement	Oral <input type="checkbox"/> Axillary <input type="checkbox"/> Other <input checked="" type="checkbox"/>
If Other, specify	TYMPANIC
Pulse ( <i>xxx</i> )	58 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	66 mmHg
Diastolic Blood Pressure units	MMHG

US3462374

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:00:14

Generated On: 11 Aug 2021 22:43:38

---

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.*

---

US3462374

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:00:14

Generated On: 11 Aug 2021 22:43:38

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) 27 AUG 2020

What was the treatment time? (00:00-23:59) 17:11 (24 HR)

Treatment Date and Time (derived) 27 AUG 2020 17:11

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

US3462374

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:00:14

Generated On: 11 Aug 2021 22:43:38

---

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	27 AUG 2020
Collection time ( <i>00:00-23:59</i> )	17:02 (24 HR)
Collection date and time (derived)	27 AUG 2020 17:02

---

US3462374

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:00:14

Generated On: 11 Aug 2021 22:43:38

---

Collection date ( <i>dd MMM yyyy</i> )			27 AUG 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:00	27 AUG 2020 17:00
Nasopharyngeal Swab 2	No		

---

US3462374

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:00:14

Generated On: 11 Aug 2021 22:43:38

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

**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 98.9 °F

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

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

PC Time Stamp 27 AUG 2020 17:43

PC Open Date & Time 27 AUG 2020 17:31

PC Close Date & Time 27 AUG 2020 20:01

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

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

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

PC Time Stamp 28 AUG 2020 04:56

PC Open Date & Time 27 AUG 2020 20:56

PC Close Date & Time 28 AUG 2020 11:59

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:43:38

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	96.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	28 AUG 2020 20:49
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE in °F** 97.9 °F

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

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

PC Time Stamp 30 AUG 2020 07:06

PC Open Date & Time 29 AUG 2020 12:00

PC Close Date & Time 30 AUG 2020 11:59

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:43:38

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.4 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	31 AUG 2020 02:24
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:43:38

**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	97.1 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	31 AUG 2020 22:06
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:43:38

---

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.9 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	02 SEP 2020 09:35
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:43:38

**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 \_\_\_\_\_  
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 02 SEP 2020 12:00  
PC Close Date & Time 03 SEP 2020 11:59

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

**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	27 AUG 2020 17:46
PC Open Date & Time	27 AUG 2020 17:31
PC Close Date & Time	27 AUG 2020 20:01

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

**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

28 AUG 2020 04:56

PC Open Date & Time

27 AUG 2020 20:56

PC Close Date & Time

28 AUG 2020 11:59

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 2

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	28 AUG 2020 20:48
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 3

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	30 AUG 2020 07:06
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

31 AUG 2020 02:24

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 5

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	31 AUG 2020 22:05
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 6

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

02 SEP 2020 09:35

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 7

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

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

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

- Yes
- No

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

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

**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

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

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

No

Yes

---

PC Time stamp	27 AUG 2020 17:47
PC Open Date & Time	27 AUG 2020 17:31
PC Close Date & Time	27 AUG 2020 20:01

---

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

**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

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

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

No

Yes

---

PC Time stamp	28 AUG 2020 04:57
PC Open Date & Time	27 AUG 2020 20:56
PC Close Date & Time	28 AUG 2020 11:59

---

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:43:38

**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

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:43:38

---

	Yes <input type="checkbox"/>
PC Time stamp	28 AUG 2020 20:49
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

---

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:43:38

**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

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:43:38

---

	Yes <input type="checkbox"/>
PC Time stamp	30 AUG 2020 07:06
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

---

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:43:38

**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

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:43:38

---

	Yes <input type="checkbox"/>
PC Time stamp	31 AUG 2020 02:25
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

---

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:43:38

**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

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:43:38

---

	Yes <input type="checkbox"/>
PC Time stamp	31 AUG 2020 22:05
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

---

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:43:38

**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

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:43:38

---

	Yes <input type="checkbox"/>
PC Time stamp	02 SEP 2020 09:36
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

---

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:43:38

**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

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:43:38

Yes

---

PC Time stamp

---

PC Open Date & Time

02 SEP 2020 12:00

---

PC Close Date & Time

03 SEP 2020 11:59

---

US3462374

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:43:38

---

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

**FATIGUE**

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

---

PC Time Stamp

03 SEP 2020 13:25

---

PC Open Date & Time

03 SEP 2020 12:00

---

PC Close Date & Time

04 SEP 2020 11:59

---

US3462374

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:43:38

---

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	03 SEP 2020 13:25
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

---

US3462374

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:00:08

Generated On: 11 Aug 2021 22:43:38

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 03 SEP 2020

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3462374

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:00:08

Generated On: 11 Aug 2021 22:43:38

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462374

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:00:08

Generated On: 11 Aug 2021 22:43:38

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 10 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3462374

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:00:08

Generated On: 11 Aug 2021 22:43:38

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462374

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:00:08

Generated On: 11 Aug 2021 22:43:38

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 17 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3462374

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:00:08

Generated On: 11 Aug 2021 22:43:38

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462374

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:00:14

Generated On: 11 Aug 2021 22:43:38

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

---

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:00:14

Generated On: 11 Aug 2021 22:43:38

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 ( <i>dd MMM yyyy</i> )	24 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	15:46 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 15:46
Temperature ( <i>xxx.x</i> )	98.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse ( <i>xxx</i> )	74 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	70 mmHg
Diastolic Blood Pressure units	MMHG

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:00:14

Generated On: 11 Aug 2021 22:43:38

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 ( <i>dd MMM yyyy</i> )	24 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	17:14 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 17:14
Temperature ( <i>xxx.x</i> )	98.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse ( <i>xxx</i> )	68 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	64 mmHg
Diastolic Blood Pressure units	MMHG

US3462374

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:00:14

Generated On: 11 Aug 2021 22:43:38

---

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.*

---

US3462374

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:00:14

Generated On: 11 Aug 2021 22:43:38

Was study treatment given? Yes   
No

If No, reason not given

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 24 SEP 2020

What was the treatment time? (00:00-23:59) 16:43 (24 HR)

Treatment Date and Time (derived) 24 SEP 2020 16:43

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

US3462374

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:00:14

Generated On: 11 Aug 2021 22:43:38

---

Was the sample collected? Yes   
No

---

Collection date (*dd MMM yyyy*) 24 SEP 2020

---

Collection time (*00:00-23:59*) 16:01 (24 HR)

---

Collection date and time (derived) 24 SEP 2020 16:01

---

US3462374

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:00:14

Generated On: 11 Aug 2021 22:43:38

---

Collection date ( <i>dd MMM yyyy</i> )			24 SEP 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:03	24 SEP 2020 16:03
Nasopharyngeal Swab 2	No		

---

US3462374

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:00:14

Generated On: 11 Aug 2021 22:43:38

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

**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 24 SEP 2020 17:12

PC Open Date & Time 24 SEP 2020 17:03

PC Close Date & Time 24 SEP 2020 19:33

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE in °F** 97.5 °F

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

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

PC Time Stamp 25 SEP 2020 08:38  
PC Open Date & Time 24 SEP 2020 20:28  
PC Close Date & Time 25 SEP 2020 11:59

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:43:38

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.5 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	25 SEP 2020 22:36
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:43:38

**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	98.2 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	27 SEP 2020 06:15
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:43:38

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.5 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	28 SEP 2020 04:53
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:43:38

**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	98.1 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	28 SEP 2020 22:58
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:43:38

**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 29 SEP 2020 12:00  
PC Close Date & Time 30 SEP 2020 11:59

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:43:38

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.9 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	30 SEP 2020 12:57
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

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

Please record - **PAIN AT INJECTION SITE.**  
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity
- Any use of prescription pain  
reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**  
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity
- Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

24 SEP 2020 17:13

PC Open Date & Time

24 SEP 2020 17:03

PC Close Date & Time

24 SEP 2020 19:33

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

**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

25 SEP 2020 08:38

PC Open Date & Time

24 SEP 2020 20:28

PC Close Date & Time

25 SEP 2020 11:59

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 2

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

3

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

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

- Yes
- No

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

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

25 SEP 2020 22:36

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 3

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

27 SEP 2020 06:15

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:43:38

**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

28 SEP 2020 04:53

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 5

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	28 SEP 2020 22:58
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 6

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

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

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

- Yes
- No

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

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 7

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	30 SEP 2020 12:58
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

**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

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

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

No

Yes

---

PC Time stamp	24 SEP 2020 17:13
PC Open Date & Time	24 SEP 2020 17:03
PC Close Date & Time	24 SEP 2020 19:33

---

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

**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

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

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

No   
Yes

---

PC Time stamp	25 SEP 2020 08:39
PC Open Date & Time	24 SEP 2020 20:28
PC Close Date & Time	25 SEP 2020 11:59

---

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:43:38

**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

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:43:38

---

	Yes <input type="checkbox"/>
PC Time stamp	25 SEP 2020 22:37
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

---

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:43:38

**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

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:43:38

---

	Yes <input type="checkbox"/>
PC Time stamp	27 SEP 2020 06:16
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

---

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:43:38

**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

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:43:38

---

	Yes <input type="checkbox"/>
PC Time stamp	28 SEP 2020 04:53
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

---

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:43:38

**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

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:43:38

---

	Yes <input type="checkbox"/>
PC Time stamp	28 SEP 2020 22:58
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

---

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:43:38

**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

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:43:38

---

Yes

---

PC Time stamp

---

PC Open Date & Time

29 SEP 2020 12:00

---

PC Close Date & Time

30 SEP 2020 11:59

---

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:43:38

**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

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:43:38

---

	Yes <input type="checkbox"/>
PC Time stamp	30 SEP 2020 12:58
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

---

US3462374

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:00:08

Generated On: 11 Aug 2021 22:43:38

Was Contact Attempted?

Yes

No

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

01 OCT 2020

Please select one status for the follow-up contact

Contact Made

Contact Not Made

Comments

*If Contact Not Made, please provide Comments*

US3462374

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:00:08

Generated On: 11 Aug 2021 22:43:38

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462374

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:00:08

Generated On: 11 Aug 2021 22:43:38

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 08 OCT 2020

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3462374

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:00:08

Generated On: 11 Aug 2021 22:43:38

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462374

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:00:08

Generated On: 11 Aug 2021 22:43:38

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3462374

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:00:08

Generated On: 11 Aug 2021 22:43:38

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462374

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:00:14

Generated On: 11 Aug 2021 22:43:38

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 29 OCT 2020

---

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

---

Folder OID VISIT3

---

US3462374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:00:14

Generated On: 11 Aug 2021 22:43:38

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) \_\_\_\_\_

US3462374

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:00:14

Generated On: 11 Aug 2021 22:43:38

---

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.*

---

US3462374

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:00:14

Generated On: 11 Aug 2021 22:43:38

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 29 OCT 2020

---

Collection time (*00:00-23:59*) 12:07 (24 HR)

---

Collection date and time (derived) 29 OCT 2020 12:07

---

US3462374

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:00:14

Generated On: 11 Aug 2021 22:43:38

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462374

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 OCT 2020 06:04:28
Patient Cloud Open Date & Time	27 OCT 2020 00:01
Patient Cloud Close Date & Time	31 OCT 2020 23:59

US3462374

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 NOV 2020 11:38:49
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3462374

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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 10 NOV 2020 18:13:16

Patient Cloud Open Date & Time 10 NOV 2020 00:01

Patient Cloud Close Date & Time 14 NOV 2020 23:59

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 89

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

No

Yes

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

No

Yes

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

Date and time of submission 24 NOV 2020 04:18:31

Patient Cloud Open Date & Time 21 NOV 2020 00:01

Patient Cloud Close Date & Time 25 NOV 2020 23:59

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 DEC 2020 20:58:32
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 12:21:40
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 10:24:59
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 DEC 2020 21:18:50
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 DEC 2020 00:04:26
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have 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	True
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	True
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	02 JAN 2021 00:36:26
Patient Cloud Open Date & Time	02 JAN 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	126 of 2447

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

---

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 JAN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JAN 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

27 JAN 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 JAN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 FEB 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 166

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

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

10 FEB 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

17 FEB 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 180

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

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

24 FEB 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 187

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

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

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

[Patient Cloud Close Date & Time](#)

03 MAR 2021 23:59

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 194

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

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

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

[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 MAR 2021 22:20:54
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 208

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

No

Yes

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

No

Yes

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

Date and time of submission 21 MAR 2021 04:59:06

Patient Cloud Open Date & Time 20 MAR 2021 00:01

Patient Cloud Close Date & Time 24 MAR 2021 23:59

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 MAR 2021 05:14:48
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 APR 2021 12:00:29
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

14 APR 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 236

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

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

---

21 APR 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 243

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

No

Yes

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

No

Yes

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

Date and time of submission 26 APR 2021 17:08:22

Patient Cloud Open Date & Time 24 APR 2021 00:01

Patient Cloud Close Date & Time 28 APR 2021 23:59

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 MAY 2021 07:42:05
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 257

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

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

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 264

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

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

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

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

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

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 JUN 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 285

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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  Yes

Have you been exposed to someone with known SARS-CoV-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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

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

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

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

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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  Yes

Have you been exposed to someone with known SARS-CoV-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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

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

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 334

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

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

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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  Yes

Have you been exposed to someone with known SARS-CoV-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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	31 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 AUG 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 348

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

---

01 SEP 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	04 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 SEP 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 SEP 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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  Yes

Have you been exposed to someone with known SARS-CoV-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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 SEP 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 404

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 OCT 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 411

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 425

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 OCT 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 432

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 446

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 453

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

---

24 NOV 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 460

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

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

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

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

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

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

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 467

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

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

<a href="#">Patient Cloud Open Date &amp; Time</a>	04 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 DEC 2021 23:59

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 DEC 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 488

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

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

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 JAN 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 516

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

---

26 JAN 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 FEB 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 FEB 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 MAR 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

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

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

---

23 MAR 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#) 06 APR 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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  Yes

Have you been exposed to someone with known SARS-CoV-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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 607

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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  Yes

Have you been exposed to someone with known SARS-CoV-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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 621

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

---

11 MAY 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

---

25 MAY 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	04 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 JUN 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUN 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 670

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#) 06 JUL 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#) 13 JUL 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 691

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

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

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 698

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

---

03 AUG 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#) 17 AUG 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

---

24 AUG 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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  Yes

Have you been exposed to someone with known SARS-CoV-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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

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

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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   
Yes

Have you been exposed to someone with known SARS-CoV-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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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  Yes

Have you been exposed to someone with known SARS-CoV-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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#) 21 SEP 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 761

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 SEP 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#) 05 OCT 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#) 19 OCT 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

DAY 789

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#) 26 OCT 2022 23:59

---

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**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  Yes

Have you been exposed to someone with known SARS-CoV-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

**US3462374**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

---

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

---

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

---

US3462374

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:43:38

---

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		11 MAR 2021 16:55:39

---

US3462374

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 19 NOV 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3462374

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462374

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 22 DEC 2020

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3462374

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462374

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 22 JAN 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3462374

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462374

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 19:26:10

Generated On: 11 Aug 2021 22:43:38

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 22 FEB 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3462374

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 19:26:10

Generated On: 11 Aug 2021 22:43:38

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462374

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 19:26:10

Generated On: 11 Aug 2021 22:43:38

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 11 MAR 2021

---

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

---

Folder OID VISIT4

---

US3462374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 14:32:13

Generated On: 11 Aug 2021 22:43:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	11 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	15:46 (24 HR)
Vital Signs Date and Time (derived)	11 MAR 2021 15:46
Temperature ( <i>xxx.x</i> )	98.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse ( <i>xxx</i> )	62 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3462374

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 19:26:10

Generated On: 11 Aug 2021 22:43:38

---

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.*

---

US3462374

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 19:26:10

Generated On: 11 Aug 2021 22:43:38

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 11 MAR 2021

---

Collection time (*00:00-23:59*) 15:27 (24 HR)

---

Collection date and time (derived) 11 MAR 2021 15:27

---

US3462374

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 19:26:10

Generated On: 11 Aug 2021 22:43:38

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462374

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 22:32:15

Generated On: 11 Aug 2021 22:43:38

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 22 APR 2021

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3462374

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:32:15

Generated On: 11 Aug 2021 22:43:38

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

**US3462374**

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

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:43:38**

---

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* \_\_\_\_\_

---

US3462374

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

---

---

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 19 Feb 2021 20:40:27

Generated On: 11 Aug 2021 22:43:38

---

Date of Contact	01 JAN 2021
Time of Contact	20:00
Date and Time of Contact (derived)	01 JAN 2021 20:00
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input checked="" type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

---

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

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

---

Date	01 JAN 2021
------	-------------

---

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

---

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

---

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

---

Temperature	101 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"/>

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

Not Done

Fatigue

None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia)

None

Mild

Moderate

Severe

Not Done

---

Body Aches

None

Mild

Moderate

Severe

Not Done

---

Headache

None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste

None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell

None

Mild

Moderate

Severe

Not Done

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

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

---

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

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"/>

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

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

---

Date	02 JAN 2021
------	-------------

---

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

---

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

---

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

---

Temperature	101 F
-------------	-------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

336 of 2447

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

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

---

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

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"/>

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

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

---

Date	03 JAN 2021
------	-------------

---

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

---

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

---

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

---

Temperature	100.3 F
-------------	---------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

340 of 2447

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

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

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

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"/>

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

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

---

Date	04 JAN 2021
------	-------------

---

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

---

O2 Saturation	99 %
---------------	------

---

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

---

Temperature	97.3 F
-------------	--------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

344 of 2447

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

	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 type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input 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"/>

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

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

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

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"/>

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

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

---

Date	05 JAN 2021
------	-------------

---

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

---

O2 Saturation	99 %
---------------	------

---

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

---

Temperature	97.3 F
-------------	--------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

348 of 2447

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

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

---

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

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"/>

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

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

Date 06 JAN 2021

Assessment Not Done False

O2 Saturation 100 %

O2 Saturation Units %

Temperature 97.3 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"/>

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

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

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

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

---

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

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"/>

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

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

---

Date	07 JAN 2021
------	-------------

---

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

---

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

---

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

---

Temperature	97.5 F
-------------	--------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

356 of 2447

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

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

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

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"/>

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

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

---

Date	08 JAN 2021
------	-------------

---

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

---

O2 Saturation	93 %
---------------	------

---

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

---

Temperature	97.6 F
-------------	--------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

360 of 2447

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

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

---

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

Symptom Day

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

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

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

---

Date	09 JAN 2021
------	-------------

---

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

---

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

---

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

---

Temperature	97.1 F
-------------	--------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003

364 of 2447

EAB) (1725)

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

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

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

Symptom Day

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

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

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

---

Date	10 JAN 2021
------	-------------

---

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

---

O2 Saturation	100 %
---------------	-------

---

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

---

Temperature	97.6 F
-------------	--------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

368 of 2447

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

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

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

Symptom Day

- Day 1
- Day 2
- Day 3
- Day 4
- Day 5
- Day 6
- Day 7
- Day 8
- Day 9
- Day 10
- Day 11
- Day 12
- Day 13
- Day 14
- Day 15
- Day 16
- Day 17
- Day 18
- Day 19
- Day 20
- Day 21
- Day 22
- Day 23
- Day 24
- Day 25
- Day 26
- Day 27
- Day 28
- Day 29
- Day 30
- Day 31
- Day 32

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

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

---

Date	11 JAN 2021
------	-------------

---

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

---

O2 Saturation	97 %
---------------	------

---

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

---

Temperature	97.7 F
-------------	--------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

372 of 2447

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

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

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

Symptom Day

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

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

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

---

Date	12 JAN 2021
------	-------------

---

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

---

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

---

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

---

Temperature	97.6 F
-------------	--------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

376 of 2447

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

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

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

Symptom Day

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

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

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

---

Date	13 JAN 2021
------	-------------

---

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

---

O2 Saturation	100 %
---------------	-------

---

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

---

Temperature	97.5 F
-------------	--------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003

380 of 2447

EAB) (1725)

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

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

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

Symptom Day

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

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

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

---

Date	14 JAN 2021
------	-------------

---

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

---

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

---

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

---

Temperature	97.0 F
-------------	--------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

384 of 2447

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

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

---

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

Symptom Day

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

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

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

---

Date	15 JAN 2021
------	-------------

---

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

---

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

---

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

---

Temperature	95.9 F
-------------	--------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

388 of 2447

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

	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 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"/>

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

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

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

Symptom Day

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

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

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

---

Date	16 JAN 2021
------	-------------

---

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

---

O2 Saturation	99 %
---------------	------

---

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

---

Temperature	97.7 F
-------------	--------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

392 of 2447

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

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

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

Symptom Day

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

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

	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 JAN 2021
------	-------------

---

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

---

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

---

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

---

Temperature	97.7 F
-------------	--------

---

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

---

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

---

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

---

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

---

PRODUCTION RELEASE (v12.003  
EAB) (1725)

396 of 2447

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

---

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

---

Body Aches None

Mild

Moderate

Severe

Not Done

---

Headache None

Mild

Moderate

Severe

Not Done

---

New Loss of Taste None

Mild

Moderate

Severe

Not Done

---

New Loss of Smell None

Mild

Moderate

Severe

Not Done

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

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

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 19 Feb 2021 20:40:27

Generated On: 11 Aug 2021 22:43:38

Date of Visit 04 JAN 2021

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 04 JAN 2021

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) 1

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 19 Feb 2021 20:40:27

Generated On: 11 Aug 2021 22:43:38

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

If Yes, provide:

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

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

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

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

If Yes, provide:

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

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

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

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

If Yes, provide:

Start Date 08 JAN 2021

End Date 08 JAN 2021

Oxygen Saturation 93 %

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

If Yes, provide:

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

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

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

Did the subject have Respiratory failure? Yes   
No

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

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

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

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 19 Feb 2021 20:40:27

Generated On: 11 Aug 2021 22:43:38

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

**Ventilator Support:**

High-Flow Oxygen? Yes   
No

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

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

Non-Invasive Ventilation? Yes   
No

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

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

Mechanical Ventilation? Yes   
No

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

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

ECMO? Yes   
No

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

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

**Evidence of Shock:**

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

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

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

Evidence of Shock Requires Vasopressors Yes   
No

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

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

Acute Renal Dysfunction? Yes   
No

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

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 19 Feb 2021 20:40:27

Generated On: 11 Aug 2021 22:43:38

Hepatic Dysfunction? Yes   
No

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

Neurologic Dysfunction? Yes   
No

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

**Evidence of Pneumonia:**

Clinical Evidence Yes   
No

Date of Assessment \_\_\_\_\_

Radiographical Evidence Yes   
No

Date of Assessment \_\_\_\_\_

Admission to an intensive care unit due to SARS-CoV-2 Yes   
No

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

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

US3462374

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 30 Mar 2021 00:58:20

Generated On: 11 Aug 2021 22:43:38

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	06 JAN 2021
Day 5	Yes	08 JAN 2021
Day 7	Yes	10 JAN 2021
Day 9	Yes	12 JAN 2021
Day 14	Yes	17 JAN 2021
Day 21	Yes	24 JAN 2021
Day 28	Yes	01 FEB 2021

US3462374

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 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	SICKD1

---

US3462374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	04 JAN 2021
Time of assessment ( <i>00:00-23:59</i> )	10:12 (24 HR)
Vital Signs Date and Time (derived)	04 JAN 2021 10:12
Height ( <i>xxx.x</i> )	191 cm
Weight ( <i>xxx.x</i> )	81 kg
Temperature ( <i>xxx.x</i> )	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	57 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3462374

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

04 JAN 2021

---

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

---

US3462374

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

---

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

Yes

No

NA (COVID-19 Negative)

---

Date of Collection

04 JAN 2021

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:40:27

Generated On: 11 Aug 2021 22:43:38

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

---

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 20:40:27

Generated On: 11 Aug 2021 22:43:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	01 FEB 2021
Time of assessment ( <i>00:00-23:59</i> )	15:00 (24 HR)
Vital Signs Date and Time (derived)	01 FEB 2021 15:00
Height ( <i>xxx.x</i> )	191 cm
Weight ( <i>xxx.x</i> )	82 kg
Temperature ( <i>xxx.x</i> )	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	62 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:40:27

Generated On: 11 Aug 2021 22:43:38

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

01 FEB 2021

---

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

---

US3462374

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 19 Feb 2021 20:40:27

Generated On: 11 Aug 2021 22:43:38

---

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

Yes

No

NA (COVID-19 Negative)

---

Date of Collection

01 FEB 2021

US3462374

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

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 19:26:10

Generated On: 11 Aug 2021 22:43:38

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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	UNBLND_DECIDE

---

US3462374

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

Form: Unblinding

Data signed: (b) (4) 19 Mar 2021 19:26:10

Generated On: 11 Aug 2021 22:43:38

Date of updated informed consent ( <i>dd MMM yyyy</i> )	11 MAR 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	11 MAR 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3462374

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Apr 2021 20:28:31

Generated On: 11 Aug 2021 22:43:38

---

Height	191 cm
Weight	81 kg
BMI (xxx.x)	22.20334

---

US3462374

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 20:28:31

Generated On: 11 Aug 2021 22:43:38

Height	191 cm
Weight	81 kg
BMI (xxx.x)	22.20334
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 MAR 2021
Time of assessment (00:00-23:59)	15:46 (24 HR)
Vital Signs Date and Time (derived)	11 MAR 2021 15:46
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3462374

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 20:28:31

Generated On: 11 Aug 2021 22:43:38

Height	191 cm
Weight	81 kg
BMI (xxx.x)	22.20334
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 MAR 2021
Time of assessment (00:00-23:59)	16:00 (24 HR)
Vital Signs Date and Time (derived)	11 MAR 2021 16:00
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3462374

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

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 19:26:10

Generated On: 11 Aug 2021 22:43:38

---

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.*

---

US3462374

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

Form: Exposure

Data signed: (b) (4) 19 Mar 2021 19:26:10

Generated On: 11 Aug 2021 22:43:38

Was study treatment given? Yes  No

If No, reason not given

Participant declined due to Adverse Event

Physician withheld dose due to Adverse Event

Death

Lost To Follow-Up

Physician Decision

Pregnancy

Protocol Deviation

Study Terminated by Sponsor

Withdrawal of Consent by Participant

Confirmed COVID-19

Other

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 11 MAR 2021

What was the treatment time? (00:00-23:59) 16:00 (24 HR)

Treatment Date and Time (derived) 11 MAR 2021 16:00

Which arm was used to give treatment? Left Arm  Right Arm

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 19:26:10

Generated On: 11 Aug 2021 22:43:38

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 11 MAR 2021

---

Collection time (*00:00-23:59*) 15:27 (24 HR)

---

Collection date and time (derived) 11 MAR 2021 15:27

---

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Mar 2021 19:26:10

Generated On: 11 Aug 2021 22:43:38

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 11 MAR 2021

---

Collection time (*00:00 - 23:59*) 15:21

---

Collection Date and Time (derived) 11 MAR 2021 15:21

---

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 19:26:10

Generated On: 11 Aug 2021 22:43:38

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3462374

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 31 Mar 2021 21:39:22

Generated On: 11 Aug 2021 22:43:38

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 18 MAR 2021

---

Please select one status for the follow-up contact Contact Made   
Contact Not Made

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3462374

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 31 Mar 2021 21:39:22

Generated On: 11 Aug 2021 22:43:38

---

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

---

US3462374

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 20:36:45

Generated On: 11 Aug 2021 22:43:38

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

---

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Apr 2021 20:36:45

Generated On: 11 Aug 2021 22:43:38

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 ( <i>dd MMM yyyy</i> )	08 APR 2021
Time of assessment ( <i>00:00-23:59</i> )	15:35 (24 HR)
Vital Signs Date and Time (derived)	08 APR 2021 15:35
Temperature ( <i>xxx.x</i> )	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	57 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	91 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	58 mmHg
Diastolic Blood Pressure units	MMHG

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Apr 2021 20:36:45

Generated On: 11 Aug 2021 22:43:38

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 ( <i>dd MMM yyyy</i> )	08 APR 2021
Time of assessment ( <i>00:00-23:59</i> )	16:42 (24 HR)
Vital Signs Date and Time (derived)	08 APR 2021 16:42
Temperature ( <i>xxx.x</i> )	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	60 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	76 mmHg
Diastolic Blood Pressure units	MMHG

US3462374

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 20:36:45

Generated On: 11 Aug 2021 22:43:38

---

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.*

---

US3462374

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 09 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:43:38

Was study treatment given? Yes   
No

If No, reason not given

Participant declined due to Adverse Event   
Physician withheld dose due to Adverse Event   
Death   
Lost To Follow-Up   
Physician Decision   
Pregnancy   
Protocol Deviation   
Study Terminated by Sponsor   
Withdrawal of Consent by Participant   
Confirmed COVID-19   
Other

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify \_\_\_\_\_

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 08 APR 2021

What was the treatment time? (00:00-23:59) 16:11 (24 HR)

Treatment Date and Time (derived) 08 APR 2021 16:11

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

US3462374

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 20:36:44

Generated On: 11 Aug 2021 22:43:38

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

**US3462374**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:43:38**

---

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* \_\_\_\_\_

---

US3462374

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

---

---

US3462374

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 20:40:27

Generated On: 11 Aug 2021 22:43:38

---

Did the participant experience any adverse events?

Yes

No

---

If Yes, enter details on the Adverse Events form.

---

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 20:40:26

Generated On: 11 Aug 2021 22:43:38

AEID	USA-US093-2021-MRNA-1273-P30 1000002
Adverse event	COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	01 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

433 of 2447

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 20:40:26

Generated On: 11 Aug 2021 22:43:38

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 20:40:27

Generated On: 11 Aug 2021 22:43:38

---

Were any prior/concomitant medications and/or vaccinations taken?

Yes

No

---

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

---

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Mar 2021 19:26:10

Generated On: 11 Aug 2021 22:43:38

Name of Medication LEXAPRO

Prophylaxis Yes   
No

Indication MILD DEPRESSION

Dose per administration 10

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

Frequency once daily   
twice daily   
three times daily   
four times daily   
every other day   
every week   
every month   
as needed   
once   
unknown   
other

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

436 of 2447

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Mar 2021 19:26:10

Generated On: 11 Aug 2021 22:43:38

	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*) 23 OCT 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Mar 2021 19:26:10

Generated On: 11 Aug 2021 22:43:38

Name of Medication TYLENOL

Prophylaxis Yes   
No

Indication INJECTION SITE PAIN

Dose per administration 650

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)

438 of 2447

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Mar 2021 19:26:10

Generated On: 11 Aug 2021 22:43:38

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify \_\_\_\_\_

Start date (*dd MMM yyyy*) 27 AUG 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 27 AUG 2020

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Mar 2021 19:26:10

Generated On: 11 Aug 2021 22:43:38

Name of Medication IBUPROFEN

Prophylaxis Yes   
No

Indication COVID-19

Dose per administration 200

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)

440 of 2447

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Mar 2021 19:26:10

Generated On: 11 Aug 2021 22:43:38

---

	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*) 01 JAN 2021

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 03 JAN 2021

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3462374

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:43:38

---

Were any concomitant procedures performed?

Yes

No

---

**If yes, please complete Concomitant Procedures form.**

---

US3462374

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:43:38

---

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

---

US3462374

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:43:38

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

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

SAEID	USA-US093-2021-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

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

SAEID USA-US093-2021-MRNA-1273-P30  
1000002

Serious Yes   
No

Death Yes   
No

Life threatening Yes   
No

Requires inpatient or prolongation of existing Hospitalization Yes   
No

Persistent or significant disability or incapacity Yes   
No

Congenital anomaly or birth defect Yes   
No

Other medically important event Yes   
No

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) 08/JAN/2021 17:35

**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

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Feb 2021 20:40:28

Generated On: 11 Aug 2021 22:43:38

SAEID USA-US093-2021-MRNA-1273-P30  
1000002

Serious Yes   
No

Death Yes   
No

Life threatening Yes   
No

Requires inpatient or prolongation of existing Hospitalization Yes   
No

Persistent or significant disability or incapacity Yes   
No

Congenital anomaly or birth defect Yes   
No

Other medically important event Yes   
No

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) 10/FEB/2021 12:10

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.** True

Audit

US3462374 (Prod: Crisor, LLC)

US3462374

Form: Participant Creation

Generated On: 11 Aug 2021 22:43:38

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'US3462374'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 23:29:27

US3462374

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:24:04

US3462374

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '27 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 23:29:28

US3462374

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[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 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Clinic (Clinic)'	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:24:04

US3462374

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered 'SCRN'	System	28 Aug 2020 00:24:04

US3462374

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:38

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered (b) (6) 1981'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 23:29:29

US3462374

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:38

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '39'	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:24:30

US3462374

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:38

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered 'YEARS'	System	28 Aug 2020 00:24:30

US3462374

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:38

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered '39'	System	28 Aug 2020 00:25:01

US3462374

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:38

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Male (M)'	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:24:30

US3462374

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:38

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:24:30

US3462374

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:38

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '1'	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:24:30

US3462374

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:38

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:24:30

US3462374

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:38

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:24:30

US3462374

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:38

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:24:30

US3462374

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:38

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:24:30

US3462374

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:24:30

US3462374

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:38

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:24:30

US3462374

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:38

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:24:30

US3462374

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:43:38

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:24:30

US3462374

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:38

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '27 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:25:01

US3462374

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:38

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered 'Aug 2020'	System	28 Aug 2020 00:25:01

US3462374

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:38

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered '2020'	System	28 Aug 2020 00:25:01

US3462374

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:38

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Amendment 3 (3)'	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:25:01

US3462374

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:38

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:25:01

US3462374

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:38

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:25:01

US3462374

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:38

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:25:01

US3462374

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:38

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:25:01

US3462374

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:38

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 23:29:28

US3462374

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:43:38

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered '1'	System	28 Aug 2020 00:25:08

US3462374

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:43:38

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:25:08

US3462374

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:43:38

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:14:51

US3462374

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\23.0.	Coder Import (b) (4)	30 Aug 2020 20:16:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Aug 2020 20:16:41
Data point term sent to Coder	System	30 Aug 2020 20:15:22
User entered 'Seasonal and Perennial Allergic Rhinitis'	(b) (4), (b) (6)	30 Aug 2020 20:15:22

US3462374

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'un UNK 1999'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:15:22

US3462374

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:38

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:15:22

US3462374

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:15:22

US3462374

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:38

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:15:22

US3462374

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:15:22

US3462374

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:38

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered 'Jan 1999'	System	30 Aug 2020 20:15:22

US3462374

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:38

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered '1999'	System	30 Aug 2020 20:15:22

US3462374

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered empty.	System	30 Aug 2020 20:15:22

US3462374

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:43:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered empty.	System	30 Aug 2020 20:15:22

US3462374

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User coded data point as SOC: Renal and urinary disorders, HLGT: Urethral disorders (excl calculi), HLT: Structural and obstructive urethral disorders (excl congenital), PT: Urethral stenosis, LLT: Urethral stenosis - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 05:18:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 05:18:08
Data point term sent to Coder	System	30 Aug 2020 20:16:23
User entered 'Narrow Urethral Opening'	(b) (4), (b) (6)	30 Aug 2020 20:16:21

US3462374

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:16:21

US3462374

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:38

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:16:21

US3462374

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:16:21

US3462374

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:38

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:16:21

US3462374

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:16:21

US3462374

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:38

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered 'Jan 2018'	System	30 Aug 2020 20:16:21

US3462374

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered '2018'	System	30 Aug 2020 20:16:21

US3462374

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered 'Jan 2018'	System	30 Aug 2020 20:16:21

US3462374

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:43:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered '2018'	System	30 Aug 2020 20:16:21

US3462374

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User coded data point as SOC: Psychiatric disorders, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	30 Aug 2020 20:18:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Aug 2020 20:18:41
Data point term sent to Coder	System	30 Aug 2020 20:17:23
User entered 'Mild Depression'	(b) (4), (b) (6)	30 Aug 2020 20:16:36

US3462374

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:16:36

US3462374

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:38

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:16:36

US3462374

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:16:36

US3462374

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:38

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:16:36

US3462374

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:16:36

US3462374

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:38

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered 'Jan 2000'	System	30 Aug 2020 20:16:36

US3462374

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:38

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered '2000'	System	30 Aug 2020 20:16:36

US3462374

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered empty.	System	30 Aug 2020 20:16:36

US3462374

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:43:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered empty.	System	30 Aug 2020 20:16:36

US3462374

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User coded data point as SOC: Surgical and medical procedures, HLGT: Renal and urinary tract therapeutic procedures, HLT: Urethral therapeutic procedures, PT: Urethral operation, LLT: Urethral operation - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 21:04:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 21:04:43
Data point term sent to Coder	System	30 Aug 2020 20:17:23
User entered 'Urethral Enlargement Surgery'	(b) (4), (b) (6)	30 Aug 2020 20:17:18

US3462374

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:17:18

US3462374

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:38

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:17:18

US3462374

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:17:18

US3462374

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:38

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:17:18

US3462374

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:17:18

US3462374

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:38

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered 'Jan 2018'	System	30 Aug 2020 20:17:18

US3462374

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered '2018'	System	30 Aug 2020 20:17:18

US3462374

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered 'Jan 2018'	System	30 Aug 2020 20:17:18

US3462374

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:43:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered '2018'	System	30 Aug 2020 20:17:18

US3462374

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\\23.0.	Coder Import (b) (4)	30 Aug 2020 20:19:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Aug 2020 20:19:41
Data point term sent to Coder	System	30 Aug 2020 20:18:24
User entered 'Vasectomy'	(b) (4), (b) (6)	30 Aug 2020 20:17:38

US3462374

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:17:38

US3462374

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:38

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:17:38

US3462374

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:17:38

US3462374

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:38

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:17:38

US3462374

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:17:38

US3462374

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:38

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered 'Jan 2018'	System	30 Aug 2020 20:17:38

US3462374

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:38

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered '2018'	System	30 Aug 2020 20:17:38

US3462374

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered 'Jan 2018'	System	30 Aug 2020 20:17:38

US3462374

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:43:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered '2018'	System	30 Aug 2020 20:17:38

US3462374

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:18:39

US3462374

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:18:39

US3462374

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '14:36'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:18:39

US3462374

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered '27 Aug 2020 14:36'	System	30 Aug 2020 20:18:39

US3462374

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '191' cm	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:18:39
DataPoint set to visible.	System	28 Aug 2020 00:25:08

US3462374

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '81' kg	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:18:39
DataPoint set to visible.	System	28 Aug 2020 00:25:08

US3462374

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered '22.20334'	System	30 Aug 2020 20:18:39
DataPoint set to visible.	System	28 Aug 2020 00:25:08

US3462374

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered 'kg/m2'	System	30 Aug 2020 20:18:39
DataPoint set to visible.	System	28 Aug 2020 00:25:08

US3462374

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 02:10:21
User entered '99.1' F		30 Aug 2020 20:18:39

US3462374

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 02:10:21
User entered 'Other (Other)'		30 Aug 2020 20:18:39

US3462374

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 02:10:21
User entered 'Tympanic'		30 Aug 2020 20:18:39

US3462374

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 02:10:21
User entered '64'		30 Aug 2020 20:18:39

US3462374

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered 'bpm'	System	30 Aug 2020 20:18:39

US3462374

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 02:10:21
User entered '16'		30 Aug 2020 20:18:39

US3462374

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered 'breaths/min'	System	30 Aug 2020 20:18:39

US3462374

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 02:10:21
User entered '132'		30 Aug 2020 20:18:39

US3462374

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered 'mmHg'	System	30 Aug 2020 20:18:39

US3462374

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 02:10:21
User entered '68'		30 Aug 2020 20:18:39

US3462374

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User entered 'mmHg'	System	30 Aug 2020 20:18:39

US3462374

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05

US3462374

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05

US3462374

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:18:49

US3462374

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:18:49

US3462374

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:38

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:20:02

US3462374

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:38

[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:20:02

US3462374

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:38

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:20:02

US3462374

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:38

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:20:02

US3462374

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:38

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:20:02

US3462374

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:38

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:20:02

US3462374

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:38

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:20:02

US3462374

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:38

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:20:02

US3462374

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:38

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:20:02

US3462374

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:38

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:20:02

US3462374

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:38

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:20:02

US3462374

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:20:02

US3462374

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:20:02

US3462374

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:38

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:20:02

US3462374

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:38

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:20:02

US3462374

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:38

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:20:02

US3462374

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:38

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:20:02

US3462374

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:38

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:20:02

US3462374

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:38

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '1'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:20:02

US3462374

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '1'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:20:02

US3462374

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:43:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:01:05
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Grocery Store and Restaurants'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:20:02

US3462374

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:25:28

US3462374

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '27 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:25:28

US3462374

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'Clinic (Clinic)'	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:25:28

US3462374

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered 'VISIT1'	System	28 Aug 2020 00:25:28

US3462374

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:38

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '27 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 23:39:20

US3462374

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:38

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '109434'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 23:39:20

US3462374

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:38

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 23:39:20

US3462374

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:38

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)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:20:56

US3462374

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:38

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)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:20:56

US3462374

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:38

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:20:56

US3462374

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:38

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:20:56

US3462374

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:38

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:20:56

US3462374

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:43:38

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:01:39
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:22:34
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:22:33

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:38

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User closed query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:14:45
Query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' answered with 'UPDATED' (Site from DM).		04 Nov 2020 02:09:35
User entered missing code ND - Not Done; reason for change Data Entry Error		04 Nov 2020 02:09:28
User opened query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).		05 Oct 2020 15:39:50
User entered '191' cm		30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 02:09:28
User entered '81' kg		30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:38

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User closed query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:14:45
Query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' answered with 'UPDATED' (Site from DM).		04 Nov 2020 02:09:35
User entered missing code ND - Not Done; reason for change Data Entry Error		04 Nov 2020 02:09:28
User opened query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).		05 Oct 2020 15:39:50
User entered '191' cm		30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 02:09:28
User entered '81' kg		30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User accepted default value 'Pre-Dose (PREDOSE)'		30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '14:36'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered '27 Aug 2020 14:36'	System	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '99.1' F	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'Tympanic'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '64'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered 'bpm'	System	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '16'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered 'breaths/min'	System	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '132'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered 'mmHg'	System	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '68'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered 'mmHg'	System	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:38

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User closed query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:14:45
Query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' answered with 'UPDATED' (Site from DM).		04 Nov 2020 02:09:35
User entered missing code ND - Not Done; reason for change Data Entry Error		04 Nov 2020 02:09:28
User opened query 'Per CDM: Per CCGs pages 15-16, as Screening and Visit 1 are on the same day, please enter Not Done in the data field of the edc for Height and Weight.' (Site from DM).		05 Oct 2020 15:39:50
User entered '191' cm		30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 02:09:28
User entered '81' kg		30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User accepted default value 'Post-Dose (POSTDOSE)'		30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '17:42'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered '27 Aug 2020 17:42'	System	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '98.9' F	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'Tympanic'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '58'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered 'bpm'	System	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '14'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered 'breaths/min'	System	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '112'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered 'mmHg'	System	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '66'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered 'mmHg'	System	30 Aug 2020 20:22:45

US3462374

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 02:10:42
User entered 'Yes (Y)'		30 Aug 2020 20:22:59

US3462374

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	04 Nov 2020 02:10:42
User entered '27 Aug 2020'		30 Aug 2020 20:22:59

US3462374

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:25:58

US3462374

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:25:58

US3462374

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:25:58

US3462374

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 00:25:58

US3462374

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '27 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:25:58

US3462374

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '17:11'	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:25:58

US3462374

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered '27 Aug 2020 17:11'	System	28 Aug 2020 00:25:58

US3462374

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Danuel Hamlin (b) (4)	28 Aug 2020 00:25:58

US3462374

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered 'ONCE'	System	28 Aug 2020 00:25:58

US3462374

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 00:25:58

US3462374

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:23:19

US3462374

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:23:19

US3462374

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '17:02'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:23:19

US3462374

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered '27 Aug 2020 17:02'	System	30 Aug 2020 20:23:19

US3462374

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:43:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:23:41

US3462374

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:43:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		30 Aug 2020 20:23:41

US3462374

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:43:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:23:41

US3462374

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:43:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '17:00'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:23:41

US3462374

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:43:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered '27 Aug 2020 17:00'	System	30 Aug 2020 20:23:41

US3462374

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:43:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		30 Aug 2020 20:23:41

US3462374

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:43:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Oct 2020 01:05:42
User entered 'Yes (Y)'		30 Aug 2020 20:23:41

US3462374

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:43:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Oct 2020 01:05:42
User entered '17:00'		30 Aug 2020 20:23:41

US3462374

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:43:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered empty.	System	13 Oct 2020 01:05:42
User entered '27 Aug 2020 17:00'	System	30 Aug 2020 20:23:41

US3462374

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Aug 2020 20:23:45

US3462374

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered '1'	System	30 Aug 2020 20:23:45

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-27T17:43:43', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '4e3f5399-00fc-4815-834c-9c7931ac8201'	System	28 Aug 2020 00:43:58
User entered 'Yes (Y)'	System	28 Aug 2020 00:43:58

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-27T17:43:48', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '4e3f5399-00fc-4815-834c-9c7931ac8201'	System	28 Aug 2020 00:43:58
User entered '98.9'	System	28 Aug 2020 00:43:58

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-27T17:43:52', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '4e3f5399-00fc-4815-834c-9c7931ac8201'	System	28 Aug 2020 00:43:58
User entered 'No (N)'	System	28 Aug 2020 00:43:58

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-27T17:43:55', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '4e3f5399-00fc-4815-834c-9c7931ac8201'	System	28 Aug 2020 00:43:58
User entered '27 Aug 2020 17:43'	System	28 Aug 2020 00:43:58

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '27 Aug 2020 17:31'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '27 Aug 2020 20:01'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T04:55:42', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'a7663129-3e2e-4c7d-b1fc-d85c018d9187'	System	28 Aug 2020 11:56:07
User entered 'Yes (Y)'	System	28 Aug 2020 11:56:07

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T04:55:49', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'a7663129-3e2e-4c7d-b1fc-d85c018d9187'	System	28 Aug 2020 11:56:07
User entered '97.9'	System	28 Aug 2020 11:56:07

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T04:55:52', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'a7663129-3e2e-4c7d-b1fc-d85c018d9187'	System	28 Aug 2020 11:56:07
User entered 'Yes (Y)'	System	28 Aug 2020 11:56:07

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
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 'ConMed added' (Site from System).	(b) (4)	16 Nov 2020 16:17:29
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).	Danuel Hamlin (b) (4)	08 Nov 2020 06:15:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T04:55:57', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'a7663129-3e2e-4c7d-b1fc-d85c018d9187'	System	28 Aug 2020 11:56:07
User entered '1'	System	28 Aug 2020 11:56:07

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T04:55:57', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'a7663129-3e2e-4c7d-b1fc-d85c018d9187'	System	28 Aug 2020 11:56:07
User entered '0'	System	28 Aug 2020 11:56:07

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T04:56:02', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'a7663129-3e2e-4c7d-b1fc-d85c018d9187'	System	28 Aug 2020 11:56:07
User entered '28 Aug 2020 04:56'	System	28 Aug 2020 11:56:07

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '27 Aug 2020 20:56'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '28 Aug 2020 11:59'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered 'Day 2'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:43:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T20:49:08', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '19826741-ad71-4cbf-9ad4-743b7894fb24'	System	29 Aug 2020 03:49:19
User entered 'Yes (Y)'	System	29 Aug 2020 03:49:19

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:43:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T20:49:12', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '19826741-ad71-4cbf-9ad4-743b7894fb24'	System	29 Aug 2020 03:49:19
User entered '96.6'	System	29 Aug 2020 03:49:19

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:43:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T20:49:14', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '19826741-ad71-4cbf-9ad4-743b7894fb24'	System	29 Aug 2020 03:49:19
User entered 'No (N)'	System	29 Aug 2020 03:49:19

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T20:49:17', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '19826741-ad71-4cbf-9ad4-743b7894fb24'	System	29 Aug 2020 03:49:19
User entered '28 Aug 2020 20:49'	System	29 Aug 2020 03:49:19

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '28 Aug 2020 12:00'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered 'Day 3'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:43:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-30T07:05:59', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'fc4b94d3-31c5-413a-983f-4b6dbf0012c1'	System	30 Aug 2020 14:06:09
User entered 'Yes (Y)'	System	30 Aug 2020 14:06:09

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:43:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-30T07:06:03', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'fc4b94d3-31c5-413a-983f-4b6dbf0012c1'	System	30 Aug 2020 14:06:09
User entered '97.9'	System	30 Aug 2020 14:06:09

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:43:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-30T07:06:05', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'fc4b94d3-31c5-413a-983f-4b6dbf0012c1'	System	30 Aug 2020 14:06:09
User entered 'No (N)'	System	30 Aug 2020 14:06:09

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-30T07:06:07', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'fc4b94d3-31c5-413a-983f-4b6dbf0012c1'	System	30 Aug 2020 14:06:09
User entered '30 Aug 2020 07:06'	System	30 Aug 2020 14:06:09

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered 'Day 4'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:43:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T02:24:11', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '390acda7-0f55-444b-9362-005515c163fa'	System	31 Aug 2020 09:24:33
User entered 'Yes (Y)'	System	31 Aug 2020 09:24:33

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:43:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T02:24:24', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '390acda7-0f55-444b-9362-005515c163fa' User entered '98.4'	System	31 Aug 2020 09:24:33
	System	31 Aug 2020 09:24:33

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:43:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T02:24:27', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '390acda7-0f55-444b-9362-005515c163fa'	System	31 Aug 2020 09:24:33
User entered 'No (N)'	System	31 Aug 2020 09:24:33

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T02:24:30', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '390acda7-0f55-444b-9362-005515c163fa'	System	31 Aug 2020 09:24:33
User entered '31 Aug 2020 02:24'	System	31 Aug 2020 09:24:33

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered 'Day 5'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:43:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T22:05:42', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'd61ceb14-a9c7-4ef8-a519-a603a49e1122'	System	01 Sep 2020 05:06:08
User entered 'Yes (Y)'	System	01 Sep 2020 05:06:08

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:43:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T22:06:00', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'd61ceb14-a9c7-4ef8-a519-a603a49e1122'	System	01 Sep 2020 05:06:08
User entered '97.1'	System	01 Sep 2020 05:06:08

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:43:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T22:06:02', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'd61ceb14-a9c7-4ef8-a519-a603a49e1122'	System	01 Sep 2020 05:06:08
User entered 'No (N)'	System	01 Sep 2020 05:06:08

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T22:06:05', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'd61ceb14-a9c7-4ef8-a519-a603a49e1122'	System	01 Sep 2020 05:06:08
User entered '31 Aug 2020 22:06'	System	01 Sep 2020 05:06:08

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered 'Day 6'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:43:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-02T09:35:25', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '12f4707f-9e9a-4db1-80df-175f7d80219e'	System	02 Sep 2020 16:35:39
User entered 'Yes (Y)'	System	02 Sep 2020 16:35:39

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:43:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-02T09:35:32', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '12f4707f-9e9a-4db1-80df-175f7d80219e'	System	02 Sep 2020 16:35:39
User entered '97.9'	System	02 Sep 2020 16:35:39

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:43:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-02T09:35:35', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '12f4707f-9e9a-4db1-80df-175f7d80219e'	System	02 Sep 2020 16:35:39
User entered 'No (N)'	System	02 Sep 2020 16:35:39

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-02T09:35:38', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '12f4707f-9e9a-4db1-80df-175f7d80219e'	System	02 Sep 2020 16:35:39
User entered '02 Sep 2020 09:35'	System	02 Sep 2020 16:35:39

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered 'Day 7'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:43:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:43:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:43:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:43:38

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:43:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-27T17:46:37', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '96d7a5bc-a2df-46c5-a0b1-522f339923ee'	System	28 Aug 2020 00:46:56
User entered 'Does not interfere with activity (2)'	System	28 Aug 2020 00:46:56

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-27T17:46:43', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '96d7a5bc-a2df-46c5-a0b1-522f339923ee'	System	28 Aug 2020 00:46:56
User entered 'No (N)'	System	28 Aug 2020 00:46:56

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-27T17:46:46', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '96d7a5bc-a2df-46c5-a0b1-522f339923ee'	System	28 Aug 2020 00:46:56
User entered 'No (N)'	System	28 Aug 2020 00:46:56

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-27T17:46:50', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '96d7a5bc-a2df-46c5-a0b1-522f339923ee'	System	28 Aug 2020 00:46:56
User entered 'None (1)'	System	28 Aug 2020 00:46:56

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-27T17:46:54', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '96d7a5bc-a2df-46c5-a0b1-522f339923ee'	System	28 Aug 2020 00:46:56
User entered '27 Aug 2020 17:46'	System	28 Aug 2020 00:46:56

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '27 Aug 2020 17:31'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '27 Aug 2020 20:01'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T04:56:09', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '6123d892-ca1d-40f9-92fa-e9e8434c9c75'	System	28 Aug 2020 11:56:37
User entered 'None (1)'	System	28 Aug 2020 11:56:37

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T04:56:13', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '6123d892-ca1d-40f9-92fa-e9e8434c9c75'	System	28 Aug 2020 11:56:37
User entered 'No (N)'	System	28 Aug 2020 11:56:37

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T04:56:21', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '6123d892-ca1d-40f9-92fa-e9e8434c9c75'	System	28 Aug 2020 11:56:37
User entered 'No (N)'	System	28 Aug 2020 11:56:37

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T04:56:30', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '6123d892-ca1d-40f9-92fa-e9e8434c9c75'	System	28 Aug 2020 11:56:37
User entered 'Does not interfere with activity (2)'	System	28 Aug 2020 11:56:37

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T04:56:34', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '6123d892-ca1d-40f9-92fa-e9e8434c9c75'	System	28 Aug 2020 11:56:37
User entered '28 Aug 2020 04:56'	System	28 Aug 2020 11:56:37

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '27 Aug 2020 20:56'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '28 Aug 2020 11:59'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered 'Day 2'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T20:48:10', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'e988ffd1-0410-4eac-b7b2-134091617be0'	System	29 Aug 2020 03:48:30
User entered 'None (1)'	System	29 Aug 2020 03:48:30

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:43:38

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T20:48:13', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'e988ffd1-0410-4eac-b7b2-134091617be0'	System	29 Aug 2020 03:48:30
User entered 'No (N)'	System	29 Aug 2020 03:48:30

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:43:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T20:48:15', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'e988ffd1-0410-4eac-b7b2-134091617be0'	System	29 Aug 2020 03:48:30
User entered 'No (N)'	System	29 Aug 2020 03:48:30

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T20:48:22', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'e988ffd1-0410-4eac-b7b2-134091617be0'	System	29 Aug 2020 03:48:30
User entered 'None (1)'	System	29 Aug 2020 03:48:30

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T20:48:28', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'e988ffd1-0410-4eac-b7b2-134091617be0'	System	29 Aug 2020 03:48:30
User entered '28 Aug 2020 20:48'	System	29 Aug 2020 03:48:30

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '28 Aug 2020 12:00'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered 'Day 3'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-30T07:06:10', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'f0649a5c-3c2b-4fde-a5e1-a25c9cb1772f' User entered 'None (1)'	System	30 Aug 2020 14:06:20
	System	30 Aug 2020 14:06:20

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:43:38

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-30T07:06:12', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'f0649a5c-3c2b-4fde-a5e1-a25c9cb1772f'	System	30 Aug 2020 14:06:20
User entered 'No (N)'	System	30 Aug 2020 14:06:20

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:43:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-30T07:06:14', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'f0649a5c-3c2b-4fde-a5e1-a25c9cb1772f'	System	30 Aug 2020 14:06:20
User entered 'No (N)'	System	30 Aug 2020 14:06:20

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-30T07:06:16', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'f0649a5c-3c2b-4fde-a5e1-a25c9cb1772f'	System	30 Aug 2020 14:06:20
User entered 'None (1)'	System	30 Aug 2020 14:06:20

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-30T07:06:18', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'f0649a5c-3c2b-4fde-a5e1-a25c9cb1772f' User entered '30 Aug 2020 07:06'	System	30 Aug 2020 14:06:20
	System	30 Aug 2020 14:06:20

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered 'Day 4'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T02:24:34', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '06836e48-9aae-49d2-a38c-fa7651bb01e6'	System	31 Aug 2020 09:24:50
User entered 'None (1)'	System	31 Aug 2020 09:24:50

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:43:38

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T02:24:38', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '06836e48-9aae-49d2-a38c-fa7651bb01e6'	System	31 Aug 2020 09:24:50
User entered 'No (N)'	System	31 Aug 2020 09:24:50

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:43:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T02:24:41', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '06836e48-9aae-49d2-a38c-fa7651bb01e6'	System	31 Aug 2020 09:24:50
User entered 'No (N)'	System	31 Aug 2020 09:24:50

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T02:24:45', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '06836e48-9aae-49d2-a38c-fa7651bb01e6'	System	31 Aug 2020 09:24:50
User entered 'None (1)'	System	31 Aug 2020 09:24:50

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T02:24:48', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '06836e48-9aae-49d2-a38c-fa7651bb01e6'	System	31 Aug 2020 09:24:50
User entered '31 Aug 2020 02:24'	System	31 Aug 2020 09:24:50

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered 'Day 5'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T22:05:10', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'f56670c2-2a4c-400e-9392-e25438cda429'	System	01 Sep 2020 05:05:21
User entered 'None (1)'	System	01 Sep 2020 05:05:21

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:43:38

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T22:05:12', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'f56670c2-2a4c-400e-9392-e25438cda429'	System	01 Sep 2020 05:05:21
User entered 'No (N)'	System	01 Sep 2020 05:05:21

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:43:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T22:05:14', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'f56670c2-2a4c-400e-9392-e25438cda429'	System	01 Sep 2020 05:05:21
User entered 'No (N)'	System	01 Sep 2020 05:05:21

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T22:05:17', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'f56670c2-2a4c-400e-9392-e25438cda429'	System	01 Sep 2020 05:05:21
User entered 'None (1)'	System	01 Sep 2020 05:05:21

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T22:05:19', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'f56670c2-2a4c-400e-9392-e25438cda429'	System	01 Sep 2020 05:05:21
User entered '31 Aug 2020 22:05'	System	01 Sep 2020 05:05:21

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered 'Day 6'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-02T09:35:41', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '939c7185-609b-4d81-9c5e-0e76781f569a'	System	02 Sep 2020 16:35:49
User entered 'None (1)'	System	02 Sep 2020 16:35:49

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:43:38

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-02T09:35:42', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '939c7185-609b-4d81-9c5e-0e76781f569a'	System	02 Sep 2020 16:35:49
User entered 'No (N)'	System	02 Sep 2020 16:35:49

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:43:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-02T09:35:44', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '939c7185-609b-4d81-9c5e-0e76781f569a'	System	02 Sep 2020 16:35:49
User entered 'No (N)'	System	02 Sep 2020 16:35:49

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-02T09:35:46', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '939c7185-609b-4d81-9c5e-0e76781f569a'	System	02 Sep 2020 16:35:49
User entered 'None (1)'	System	02 Sep 2020 16:35:49

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-02T09:35:47', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '939c7185-609b-4d81-9c5e-0e76781f569a'	System	02 Sep 2020 16:35:49
User entered '02 Sep 2020 09:35'	System	02 Sep 2020 16:35:49

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered 'Day 7'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:43:38

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:43:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-27T17:47:04', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '93baf21b-f8dc-4e94-a282-d302ce60ca06'	System	28 Aug 2020 00:47:26
User entered 'No interference with activity (1)'	System	28 Aug 2020 00:47:26

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-27T17:47:09', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '93baf21b-f8dc-4e94-a282-d302ce60ca06'	System	28 Aug 2020 00:47:26
User entered 'None (0)'	System	28 Aug 2020 00:47:26

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-27T17:47:12', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '93baf21b-f8dc-4e94-a282-d302ce60ca06'	System	28 Aug 2020 00:47:26
User entered 'None (0)'	System	28 Aug 2020 00:47:26

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-27T17:47:14', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '93baf21b-f8dc-4e94-a282-d302ce60ca06'	System	28 Aug 2020 00:47:26
User entered 'None (0)'	System	28 Aug 2020 00:47:26

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-27T17:47:16', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '93baf21b-f8dc-4e94-a282-d302ce60ca06'	System	28 Aug 2020 00:47:26
User entered 'None (0)'	System	28 Aug 2020 00:47:26

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-27T17:47:18', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '93baf21b-f8dc-4e94-a282-d302ce60ca06'	System	28 Aug 2020 00:47:26
User entered 'None (0)'	System	28 Aug 2020 00:47:26

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-27T17:47:20', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '93baf21b-f8dc-4e94-a282-d302ce60ca06'	System	28 Aug 2020 00:47:26
User entered 'No (N)'	System	28 Aug 2020 00:47:26

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-27T17:47:23', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '93baf21b-f8dc-4e94-a282-d302ce60ca06'	System	28 Aug 2020 00:47:26
User entered '27 Aug 2020 17:47'	System	28 Aug 2020 00:47:26

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '27 Aug 2020 17:31'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '27 Aug 2020 20:01'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T04:56:44', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'c959dba6-6d89-4729-b3b1-5899c8eb3744'	System	28 Aug 2020 11:57:06
User entered 'No interference with activity (1)'	System	28 Aug 2020 11:57:06

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T04:56:47', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'c959dba6-6d89-4729-b3b1-5899c8eb3744'	System	28 Aug 2020 11:57:06
User entered 'No interference with activity (1)'	System	28 Aug 2020 11:57:06

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T04:56:50', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'c959dba6-6d89-4729-b3b1-5899c8eb3744'	System	28 Aug 2020 11:57:06
User entered 'None (0)'	System	28 Aug 2020 11:57:06

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T04:56:53', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'c959dba6-6d89-4729-b3b1-5899c8eb3744'	System	28 Aug 2020 11:57:06
User entered 'None (0)'	System	28 Aug 2020 11:57:06

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T04:56:55', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'c959dba6-6d89-4729-b3b1-5899c8eb3744'	System	28 Aug 2020 11:57:06
User entered 'None (0)'	System	28 Aug 2020 11:57:06

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T04:56:58', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'c959dba6-6d89-4729-b3b1-5899c8eb3744'	System	28 Aug 2020 11:57:06
User entered 'None (0)'	System	28 Aug 2020 11:57:06

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T04:57:02', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'c959dba6-6d89-4729-b3b1-5899c8eb3744'	System	28 Aug 2020 11:57:06
User entered 'No (N)'	System	28 Aug 2020 11:57:06

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T04:57:04', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'c959dba6-6d89-4729-b3b1-5899c8eb3744'	System	28 Aug 2020 11:57:06
User entered '28 Aug 2020 04:57'	System	28 Aug 2020 11:57:06

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '27 Aug 2020 20:56'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '28 Aug 2020 11:59'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered 'Day 2'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:43:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T20:48:32', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '7b6104bf-c187-4fc0-88ac-16889a620366'	System	29 Aug 2020 03:49:07
User entered 'No interference with activity (1)'	System	29 Aug 2020 03:49:07

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:43:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T20:48:36', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '7b6104bf-c187-4fc0-88ac-16889a620366'	System	29 Aug 2020 03:49:07
User entered 'No interference with activity (1)'	System	29 Aug 2020 03:49:07

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:43:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T20:48:42', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '7b6104bf-c187-4fc0-88ac-16889a620366'	System	29 Aug 2020 03:49:07
User entered 'None (0)'	System	29 Aug 2020 03:49:07

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:43:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T20:48:45', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '7b6104bf-c187-4fc0-88ac-16889a620366'	System	29 Aug 2020 03:49:07
User entered 'None (0)'	System	29 Aug 2020 03:49:07

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:43:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T20:48:47', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '7b6104bf-c187-4fc0-88ac-16889a620366'	System	29 Aug 2020 03:49:07
User entered 'None (0)'	System	29 Aug 2020 03:49:07

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:43:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T20:48:59', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '7b6104bf-c187-4fc0-88ac-16889a620366'	System	29 Aug 2020 03:49:07
User entered 'None (0)'	System	29 Aug 2020 03:49:07

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T20:49:01', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '7b6104bf-c187-4fc0-88ac-16889a620366'	System	29 Aug 2020 03:49:07
User entered 'No (N)'	System	29 Aug 2020 03:49:07

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:43:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-28T20:49:03', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '7b6104bf-c187-4fc0-88ac-16889a620366'	System	29 Aug 2020 03:49:07
User entered '28 Aug 2020 20:49'	System	29 Aug 2020 03:49:07

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '28 Aug 2020 12:00'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered 'Day 3'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:43:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-30T07:06:21', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '7a364c47-db57-4e94-b07e-98051e0cfbe1'	System	30 Aug 2020 14:06:38
User entered 'None (0)'	System	30 Aug 2020 14:06:38

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:43:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-30T07:06:23', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '7a364c47-db57-4e94-b07e-98051e0cfbe1'	System	30 Aug 2020 14:06:38
User entered 'None (0)'	System	30 Aug 2020 14:06:38

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:43:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-30T07:06:24', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '7a364c47-db57-4e94-b07e-98051e0cfbe1'	System	30 Aug 2020 14:06:38
User entered 'None (0)'	System	30 Aug 2020 14:06:38

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:43:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-30T07:06:25', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '7a364c47-db57-4e94-b07e-98051e0cfbe1'	System	30 Aug 2020 14:06:38
User entered 'None (0)'	System	30 Aug 2020 14:06:38

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:43:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-30T07:06:27', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '7a364c47-db57-4e94-b07e-98051e0cfbe1'	System	30 Aug 2020 14:06:38
User entered 'None (0)'	System	30 Aug 2020 14:06:38

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:43:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-30T07:06:28', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '7a364c47-db57-4e94-b07e-98051e0cfbe1'	System	30 Aug 2020 14:06:38
User entered 'None (0)'	System	30 Aug 2020 14:06:38

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-30T07:06:30', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '7a364c47-db57-4e94-b07e-98051e0cfbe1'	System	30 Aug 2020 14:06:38
User entered 'No (N)'	System	30 Aug 2020 14:06:38

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:43:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-30T07:06:34', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '7a364c47-db57-4e94-b07e-98051e0cfbe1'	System	30 Aug 2020 14:06:38
User entered '30 Aug 2020 07:06'	System	30 Aug 2020 14:06:38

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered 'Day 4'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:43:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T02:24:54', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'b1f2e867-973a-4380-a3ef-fe620eb7be5f'	System	31 Aug 2020 09:25:15
User entered 'None (0)'	System	31 Aug 2020 09:25:15

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:43:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T02:24:59', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'b1f2e867-973a-4380-a3ef-fe620eb7be5f'	System	31 Aug 2020 09:25:15
User entered 'None (0)'	System	31 Aug 2020 09:25:15

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:43:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T02:25:01', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'b1f2e867-973a-4380-a3ef-fe620eb7be5f'	System	31 Aug 2020 09:25:15
User entered 'None (0)'	System	31 Aug 2020 09:25:15

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:43:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T02:25:03', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'b1f2e867-973a-4380-a3ef-fe620eb7be5f'	System	31 Aug 2020 09:25:15
User entered 'None (0)'	System	31 Aug 2020 09:25:15

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:43:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T02:25:06', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'b1f2e867-973a-4380-a3ef-fe620eb7be5f'	System	31 Aug 2020 09:25:15
User entered 'None (0)'	System	31 Aug 2020 09:25:15

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:43:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T02:25:08', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'b1f2e867-973a-4380-a3ef-fe620eb7be5f'	System	31 Aug 2020 09:25:15
User entered 'None (0)'	System	31 Aug 2020 09:25:15

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T02:25:11', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'b1f2e867-973a-4380-a3ef-fe620eb7be5f'	System	31 Aug 2020 09:25:15
User entered 'No (N)'	System	31 Aug 2020 09:25:15

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:43:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T02:25:14', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'b1f2e867-973a-4380-a3ef-fe620eb7be5f'	System	31 Aug 2020 09:25:15
User entered '31 Aug 2020 02:25'	System	31 Aug 2020 09:25:15

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered 'Day 5'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:43:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T22:05:22', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'a5d12910-79e5-4868-b76e-fe9559d4891b'	System	01 Sep 2020 05:05:42
User entered 'None (0)'	System	01 Sep 2020 05:05:42

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:43:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T22:05:26', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'a5d12910-79e5-4868-b76e-fe9559d4891b'	System	01 Sep 2020 05:05:42
User entered 'Some interference with activity (2)'	System	01 Sep 2020 05:05:42

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:43:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T22:05:28', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'a5d12910-79e5-4868-b76e-fe9559d4891b'	System	01 Sep 2020 05:05:42
User entered 'None (0)'	System	01 Sep 2020 05:05:42

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:43:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T22:05:29', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'a5d12910-79e5-4868-b76e-fe9559d4891b'	System	01 Sep 2020 05:05:42
User entered 'None (0)'	System	01 Sep 2020 05:05:42

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:43:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T22:05:31', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'a5d12910-79e5-4868-b76e-fe9559d4891b'	System	01 Sep 2020 05:05:42
User entered 'None (0)'	System	01 Sep 2020 05:05:42

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:43:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T22:05:32', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'a5d12910-79e5-4868-b76e-fe9559d4891b'	System	01 Sep 2020 05:05:42
User entered 'None (0)'	System	01 Sep 2020 05:05:42

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T22:05:34', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'a5d12910-79e5-4868-b76e-fe9559d4891b'	System	01 Sep 2020 05:05:42
User entered 'No (N)'	System	01 Sep 2020 05:05:42

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:43:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-08-31T22:05:36', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'a5d12910-79e5-4868-b76e-fe9559d4891b'	System	01 Sep 2020 05:05:42
User entered '31 Aug 2020 22:05'	System	01 Sep 2020 05:05:42

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered 'Day 6'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:43:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-02T09:35:51', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '30d81395-a2cb-4462-95d0-fb3975bb2e61'	System	02 Sep 2020 16:36:12
User entered 'None (0)'	System	02 Sep 2020 16:36:12

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:43:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-02T09:35:58', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '30d81395-a2cb-4462-95d0-fb3975bb2e61'	System	02 Sep 2020 16:36:12
User entered 'Some interference with activity (2)'	System	02 Sep 2020 16:36:12

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:43:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-02T09:36:01', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '30d81395-a2cb-4462-95d0-fb3975bb2e61'	System	02 Sep 2020 16:36:12
User entered 'None (0)'	System	02 Sep 2020 16:36:12

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:43:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-02T09:36:03', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '30d81395-a2cb-4462-95d0-fb3975bb2e61'	System	02 Sep 2020 16:36:12
User entered 'None (0)'	System	02 Sep 2020 16:36:12

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:43:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-02T09:36:05', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '30d81395-a2cb-4462-95d0-fb3975bb2e61'	System	02 Sep 2020 16:36:12
User entered 'None (0)'	System	02 Sep 2020 16:36:12

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:43:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-02T09:36:07', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '30d81395-a2cb-4462-95d0-fb3975bb2e61'	System	02 Sep 2020 16:36:12
User entered 'None (0)'	System	02 Sep 2020 16:36:12

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-02T09:36:09', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '30d81395-a2cb-4462-95d0-fb3975bb2e61'	System	02 Sep 2020 16:36:12
User entered 'No (N)'	System	02 Sep 2020 16:36:12

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:43:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-02T09:36:11', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '30d81395-a2cb-4462-95d0-fb3975bb2e61'	System	02 Sep 2020 16:36:12
User entered '02 Sep 2020 09:36'	System	02 Sep 2020 16:36:12

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered 'Day 7'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:43:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:43:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:43:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:43:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:43:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:43:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:43:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 00:25:58

US3462374

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	02 Sep 2020 16:36:12
User entered 'Day 8'	System	02 Sep 2020 16:36:12

US3462374

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-03T13:25:06', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '09ea37d1-7770-4755-984e-19fd97ac7964'	System	03 Sep 2020 20:25:11
User entered 'None (0)'	System	03 Sep 2020 20:25:11

US3462374

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-03T13:25:08', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '09ea37d1-7770-4755-984e-19fd97ac7964'	System	03 Sep 2020 20:25:11
User entered '03 Sep 2020 13:25'	System	03 Sep 2020 20:25:11

US3462374

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 16:36:12

US3462374

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 16:36:12

US3462374

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	02 Sep 2020 16:36:12
User entered 'Day 8'	System	02 Sep 2020 16:36:12

US3462374

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-03T13:25:13', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'bbdf24e2-3404-4d15-8570-0893c6025988'	System	03 Sep 2020 20:25:17
User entered 'No (N)'	System	03 Sep 2020 20:25:17

US3462374

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:43:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-03T13:25:14', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'bbdf24e2-3404-4d15-8570-0893c6025988'	System	03 Sep 2020 20:25:17
User entered '03 Sep 2020 13:25'	System	03 Sep 2020 20:25:17

US3462374

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 16:36:12

US3462374

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 16:36:12

US3462374

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	08 Sep 2020 03:16:38

US3462374

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '03 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	08 Sep 2020 03:16:38

US3462374

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danuel Hamlin (b) (4)	08 Sep 2020 03:16:38

US3462374

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	08 Sep 2020 03:16:38

US3462374

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	08 Sep 2020 03:16:46

US3462374

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered '1'	System	08 Sep 2020 03:16:46

US3462374

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 23:54:18

US3462374

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '10 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 23:54:18

US3462374

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 23:54:18

US3462374

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 23:54:18

US3462374

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 23:54:24

US3462374

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered 'I'	System	24 Sep 2020 23:54:24

US3462374

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 23:54:48

US3462374

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '17 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 23:54:48

US3462374

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 23:54:48

US3462374

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 23:54:48

US3462374

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 23:54:57

US3462374

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered '1'	System	24 Sep 2020 23:54:57

US3462374

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 23:55:31

US3462374

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '24 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 23:55:31

US3462374

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'Clinic (Clinic)'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 23:55:31

US3462374

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered 'VISIT2'	System	24 Sep 2020 23:55:31

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User accepted default value 'Pre-Dose (PREDOSE)'		27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '15:46'	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered '24 Sep 2020 15:46'	System	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'TYMPANIC'	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '74'	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered 'bpm'	System	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '16'	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered 'breaths/min'	System	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '100'	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered 'mmHg'	System	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '70'	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered 'mmHg'	System	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User accepted default value 'Post-Dose (POSTDOSE)'		27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '17:14'	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered '24 Sep 2020 17:14'	System	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '98.9' F	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'TYMPANIC'	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '68'	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered 'bpm'	System	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '16'	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered 'breaths/min'	System	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '116'	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered 'mmHg'	System	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '64'	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered 'mmHg'	System	27 Sep 2020 20:03:00

US3462374

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:03:08

US3462374

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:03:08

US3462374

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 23:56:35

US3462374

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 23:56:35

US3462374

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 23:56:35

US3462374

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered 'MRNA-1273 OR PLACEBO'	System	24 Sep 2020 23:56:35

US3462374

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '24 Sep 2020'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 23:56:35

US3462374

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '16:43'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 23:56:35

US3462374

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered '24 Sep 2020 16:43'	System	24 Sep 2020 23:56:35

US3462374

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Danuel Hamlin (b) (4)	24 Sep 2020 23:56:35

US3462374

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered 'ONCE'	System	24 Sep 2020 23:56:35

US3462374

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered 'INTRAMUSCULAR'	System	24 Sep 2020 23:56:35

US3462374

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:03:25

US3462374

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:03:25

US3462374

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '16:01'	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:03:25

US3462374

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered '24 Sep 2020 16:01'	System	27 Sep 2020 20:03:25

US3462374

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:43:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:03:49

US3462374

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:43:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		27 Sep 2020 20:03:49

US3462374

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:43:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:03:49

US3462374

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:43:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '16:03'	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:03:49

US3462374

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:43:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered '24 Sep 2020 16:03'	System	27 Sep 2020 20:03:49

US3462374

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:43:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		27 Sep 2020 20:03:49

US3462374

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:43:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Oct 2020 01:06:01
User entered 'Yes (Y)'		27 Sep 2020 20:03:49

US3462374

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:43:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered empty; reason for change Data Entry Error	(b) (4) (d) (4), (b) (6)	13 Oct 2020 01:06:01
User entered '16:03'		27 Sep 2020 20:03:49

US3462374

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:43:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered empty.	System	13 Oct 2020 01:06:01
User entered '24 Sep 2020 16:03'	System	27 Sep 2020 20:03:49

US3462374

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Sep 2020 20:03:55

US3462374

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered '1'	System	27 Sep 2020 20:03:55

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	24 Sep 2020 23:56:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-24T17:12:34', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '1fe7fdf6-4d61-4772-bae1-5fa54a5a2ab3'	System	25 Sep 2020 00:12:52
User entered 'Yes (Y)'	System	25 Sep 2020 00:12:52

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-24T17:12:39', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '1fe7fdf6-4d61-4772-bae1-5fa54a5a2ab3'	System	25 Sep 2020 00:12:52
User entered '98.2'	System	25 Sep 2020 00:12:52

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-24T17:12:42', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '1fe7fdf6-4d61-4772-bae1-5fa54a5a2ab3'	System	25 Sep 2020 00:12:52
User entered 'No (N)'	System	25 Sep 2020 00:12:52

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-24T17:12:49', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '1fe7fdf6-4d61-4772-bae1-5fa54a5a2ab3'	System	25 Sep 2020 00:12:52
User entered '24 Sep 2020 17:12'	System	25 Sep 2020 00:12:52

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '24 Sep 2020 17:03'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '24 Sep 2020 19:33'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	24 Sep 2020 23:56:35
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T08:38:31', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '7cc800ff-56fc-4be4-ba92-6fa778e0aa58'	System	25 Sep 2020 15:38:47
User entered 'Yes (Y)'	System	25 Sep 2020 15:38:47

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T08:38:35', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '7cc800ff-56fc-4be4-ba92-6fa778e0aa58'	System	25 Sep 2020 15:38:47
User entered '97.5'	System	25 Sep 2020 15:38:47

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T08:38:38', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '7cc800ff-56fc-4be4-ba92-6fa778e0aa58'	System	25 Sep 2020 15:38:47
User entered 'No (N)'	System	25 Sep 2020 15:38:47

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T08:38:44', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '7cc800ff-56fc-4be4-ba92-6fa778e0aa58'	System	25 Sep 2020 15:38:47
User entered '25 Sep 2020 08:38'	System	25 Sep 2020 15:38:47

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '24 Sep 2020 20:28'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	24 Sep 2020 23:56:35
User entered 'Day 2'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:43:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T22:35:54', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '20cc6af3-497f-4d8d-bbdf-3b94dc8c779f'	System	26 Sep 2020 05:36:09
User entered 'Yes (Y)'	System	26 Sep 2020 05:36:09

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:43:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T22:35:58', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '20cc6af3-497f-4d8d-bbdf-3b94dc8c779f'	System	26 Sep 2020 05:36:09
User entered '97.5'	System	26 Sep 2020 05:36:09

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:43:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T22:36:00', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '20cc6af3-497f-4d8d-bbdf-3b94dc8c779f'	System	26 Sep 2020 05:36:09
User entered 'No (N)'	System	26 Sep 2020 05:36:09

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T22:36:03', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '20cc6af3-497f-4d8d-bbdf-3b94dc8c779f'	System	26 Sep 2020 05:36:09
User entered '25 Sep 2020 22:36'	System	26 Sep 2020 05:36:09

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	24 Sep 2020 23:56:35
User entered 'Day 3'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:43:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-27T06:15:13', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'aaefd6a2-100f-4c91-b24a-03e266b7d909'	System	27 Sep 2020 13:15:39
User entered 'Yes (Y)'	System	27 Sep 2020 13:15:39

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:43:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-27T06:15:18', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'aaefd6a2-100f-4c91-b24a-03e266b7d909'	System	27 Sep 2020 13:15:39
User entered '98.2'	System	27 Sep 2020 13:15:39

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:43:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-27T06:15:34', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'aaefd6a2-100f-4c91-b24a-03e266b7d909'	System	27 Sep 2020 13:15:39
User entered 'No (N)'	System	27 Sep 2020 13:15:39

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-27T06:15:37', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'aaefd6a2-100f-4c91-b24a-03e266b7d909'	System	27 Sep 2020 13:15:39
User entered '27 Sep 2020 06:15'	System	27 Sep 2020 13:15:39

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	24 Sep 2020 23:56:35
User entered 'Day 4'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:43:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T04:53:04', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'cb5d5a91-42a7-4774-90f6-c460792c598f' User entered 'Yes (Y)'	System	28 Sep 2020 11:53:15
	System	28 Sep 2020 11:53:15

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:43:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T04:53:08', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'cb5d5a91-42a7-4774-90f6-c460792c598f' User entered '97.5'	System	28 Sep 2020 11:53:15
	System	28 Sep 2020 11:53:15

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:43:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T04:53:10', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'cb5d5a91-42a7-4774-90f6-c460792c598f'	System	28 Sep 2020 11:53:15
User entered 'No (N)'	System	28 Sep 2020 11:53:15

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T04:53:13', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'cb5d5a91-42a7-4774-90f6-c460792c598f' User entered '28 Sep 2020 04:53'	System	28 Sep 2020 11:53:15
	System	28 Sep 2020 11:53:15

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	24 Sep 2020 23:56:35
User entered 'Day 5'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:43:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T22:58:17', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'aa5858cd-f6f4-43e5-98d1-d78c0214b3c6'	System	29 Sep 2020 05:58:28
User entered 'Yes (Y)'	System	29 Sep 2020 05:58:28

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:43:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T22:58:21', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'aa5858cd-f6f4-43e5-98d1-d78c0214b3c6'	System	29 Sep 2020 05:58:28
User entered '98.1'	System	29 Sep 2020 05:58:28

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:43:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T22:58:23', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'aa5858cd-f6f4-43e5-98d1-d78c0214b3c6'	System	29 Sep 2020 05:58:28
User entered 'No (N)'	System	29 Sep 2020 05:58:28

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T22:58:25', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'aa5858cd-f6f4-43e5-98d1-d78c0214b3c6'	System	29 Sep 2020 05:58:28
User entered '28 Sep 2020 22:58'	System	29 Sep 2020 05:58:28

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	24 Sep 2020 23:56:35
User entered 'Day 6'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:43:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:43:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:43:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:43:38

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:43:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	24 Sep 2020 23:56:35
User entered 'Day 7'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:43:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-30T12:57:43', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '27ffc0e9-03c9-44cb-bcc6-d5a53ee1cab3'	System	30 Sep 2020 19:57:59
User entered 'Yes (Y)'	System	30 Sep 2020 19:57:59

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:43:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-30T12:57:48', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '27ffc0e9-03c9-44cb-bcc6-d5a53ee1cab3'	System	30 Sep 2020 19:57:59
User entered '97.9'	System	30 Sep 2020 19:57:59

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:43:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-30T12:57:50', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '27ffc0e9-03c9-44cb-bcc6-d5a53ee1cab3'	System	30 Sep 2020 19:57:59
User entered 'No (N)'	System	30 Sep 2020 19:57:59

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-30T12:57:52', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '27ffc0e9-03c9-44cb-bcc6-d5a53ee1cab3'	System	30 Sep 2020 19:57:59
User entered '30 Sep 2020 12:57'	System	30 Sep 2020 19:57:59

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	24 Sep 2020 23:56:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-24T17:12:56', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'b75646ef-104a-4cd2-991e-3ef96bb503c6'	System	25 Sep 2020 00:13:20
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 00:13:20

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-24T17:13:04', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'b75646ef-104a-4cd2-991e-3ef96bb503c6'	System	25 Sep 2020 00:13:20
User entered 'No (N)'	System	25 Sep 2020 00:13:20

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-24T17:13:09', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'b75646ef-104a-4cd2-991e-3ef96bb503c6'	System	25 Sep 2020 00:13:20
User entered 'No (N)'	System	25 Sep 2020 00:13:20

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-24T17:13:15', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'b75646ef-104a-4cd2-991e-3ef96bb503c6'	System	25 Sep 2020 00:13:20
User entered 'None (1)'	System	25 Sep 2020 00:13:20

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-24T17:13:18', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'b75646ef-104a-4cd2-991e-3ef96bb503c6'	System	25 Sep 2020 00:13:20
User entered '24 Sep 2020 17:13'	System	25 Sep 2020 00:13:20

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '24 Sep 2020 17:03'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '24 Sep 2020 19:33'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	24 Sep 2020 23:56:35
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T08:38:47', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'd38ad880-7835-45da-bcf3-b3c4783b1603'	System	25 Sep 2020 15:38:58
User entered 'None (1)'	System	25 Sep 2020 15:38:58

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T08:38:49', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'd38ad880-7835-45da-bcf3-b3c4783b1603'	System	25 Sep 2020 15:38:58
User entered 'No (N)'	System	25 Sep 2020 15:38:58

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T08:38:51', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'd38ad880-7835-45da-bcf3-b3c4783b1603'	System	25 Sep 2020 15:38:58
User entered 'No (N)'	System	25 Sep 2020 15:38:58

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T08:38:53', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'd38ad880-7835-45da-bcf3-b3c4783b1603'	System	25 Sep 2020 15:38:58
User entered 'None (1)'	System	25 Sep 2020 15:38:58

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T08:38:56', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'd38ad880-7835-45da-bcf3-b3c4783b1603'	System	25 Sep 2020 15:38:58
User entered '25 Sep 2020 08:38'	System	25 Sep 2020 15:38:58

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '24 Sep 2020 20:28'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	24 Sep 2020 23:56:35
User entered 'Day 2'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T22:36:08', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '1efebd7d-9eb7-4bcb-a491-5d8c69a88c5b' User entered 'None (1)'	System	26 Sep 2020 05:36:30
	System	26 Sep 2020 05:36:30

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:43:38

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T22:36:13', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '1efebd7d-9eb7-4bcb-a491-5d8c69a88c5b'	System	26 Sep 2020 05:36:30
User entered 'Yes (Y)'	System	26 Sep 2020 05:36:30

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T22:36:21', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '1efebd7d-9eb7-4bcb-a491-5d8c69a88c5b' User entered '3'	System	26 Sep 2020 05:36:30
	System	26 Sep 2020 05:36:30

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:43:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T22:36:23', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '1efebd7d-9eb7-4bcb-a491-5d8c69a88c5b'	System	26 Sep 2020 05:36:30
User entered 'No (N)'	System	26 Sep 2020 05:36:30

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T22:36:25', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '1efebd7d-9eb7-4bcb-a491-5d8c69a88c5b' User entered 'None (1)'	System	26 Sep 2020 05:36:30
	System	26 Sep 2020 05:36:30

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T22:36:27', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '1efebd7d-9eb7-4bcb-a491-5d8c69a88c5b'	System	26 Sep 2020 05:36:30
User entered '25 Sep 2020 22:36'	System	26 Sep 2020 05:36:30

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	24 Sep 2020 23:56:35
User entered 'Day 3'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-27T06:15:40', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '185c01ce-89a9-4e2a-99c3-12f9ae483d'	System	27 Sep 2020 13:15:51
User entered 'None (1)'	System	27 Sep 2020 13:15:51

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:43:38

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-27T06:15:42', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '185c01ce-89a9-4e2a-99c3-12f9aeee483d'	System	27 Sep 2020 13:15:51
User entered 'No (N)'	System	27 Sep 2020 13:15:51

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:43:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-27T06:15:44', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '185c01ce-89a9-4e2a-99c3-12f9aeee483d'	System	27 Sep 2020 13:15:51
User entered 'No (N)'	System	27 Sep 2020 13:15:51

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-27T06:15:48', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '185c01ce-89a9-4e2a-99c3-12f9ae483d'	System	27 Sep 2020 13:15:51
User entered 'None (1)'	System	27 Sep 2020 13:15:51

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-27T06:15:50', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '185c01ce-89a9-4e2a-99c3-12f9aeee483d'	System	27 Sep 2020 13:15:51
User entered '27 Sep 2020 06:15'	System	27 Sep 2020 13:15:51

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	24 Sep 2020 23:56:35
User entered 'Day 4'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T04:53:16', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '2bf2e21d-be82-4d4f-a4fd-5cd63d0f2e22'	System	28 Sep 2020 11:53:26
User entered 'None (1)'	System	28 Sep 2020 11:53:26

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:43:38

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T04:53:18', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '2bf2e21d-be82-4d4f-a4fd-5cd63d0f2e22'	System	28 Sep 2020 11:53:26
User entered 'No (N)'	System	28 Sep 2020 11:53:26

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:43:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T04:53:20', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '2bf2e21d-be82-4d4f-a4fd-5cd63d0f2e22'	System	28 Sep 2020 11:53:26
User entered 'No (N)'	System	28 Sep 2020 11:53:26

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T04:53:22', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '2bf2e21d-be82-4d4f-a4fd-5cd63d0f2e22'	System	28 Sep 2020 11:53:26
User entered 'None (1)'	System	28 Sep 2020 11:53:26

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T04:53:24', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '2bf2e21d-be82-4d4f-a4fd-5cd63d0f2e22'	System	28 Sep 2020 11:53:26
User entered '28 Sep 2020 04:53'	System	28 Sep 2020 11:53:26

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	24 Sep 2020 23:56:35
User entered 'Day 5'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T22:58:28', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '52c63c34-625a-4d64-97de-3144a15c63b2'	System	29 Sep 2020 05:58:36
User entered 'None (1)'	System	29 Sep 2020 05:58:36

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:43:38

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T22:58:29', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '52c63c34-625a-4d64-97de-3144a15c63b2'	System	29 Sep 2020 05:58:36
User entered 'No (N)'	System	29 Sep 2020 05:58:36

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:43:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T22:58:31', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '52c63c34-625a-4d64-97de-3144a15c63b2'	System	29 Sep 2020 05:58:36
User entered 'No (N)'	System	29 Sep 2020 05:58:36

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T22:58:32', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '52c63c34-625a-4d64-97de-3144a15c63b2'	System	29 Sep 2020 05:58:36
User entered 'None (1)'	System	29 Sep 2020 05:58:36

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T22:58:34', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '52c63c34-625a-4d64-97de-3144a15c63b2'	System	29 Sep 2020 05:58:36
User entered '28 Sep 2020 22:58'	System	29 Sep 2020 05:58:36

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	24 Sep 2020 23:56:35
User entered 'Day 6'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:43:38

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:43:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	24 Sep 2020 23:56:35
User entered 'Day 7'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-30T12:57:55', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'c748fed1-2cf6-4cc2-8c22-0dc40aef3791'	System	30 Sep 2020 19:58:07
User entered 'None (1)'	System	30 Sep 2020 19:58:07

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:43:38

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-30T12:57:57', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'c748fed1-2cf6-4cc2-8c22-0dc40aef3791'	System	30 Sep 2020 19:58:07
User entered 'No (N)'	System	30 Sep 2020 19:58:07

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:43:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-30T12:57:58', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'c748fed1-2cf6-4cc2-8c22-0dc40aef3791'	System	30 Sep 2020 19:58:07
User entered 'No (N)'	System	30 Sep 2020 19:58:07

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-30T12:58:00', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'c748fed1-2cf6-4cc2-8c22-0dc40aef3791'	System	30 Sep 2020 19:58:07
User entered 'None (1)'	System	30 Sep 2020 19:58:07

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:43:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-30T12:58:01', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'c748fed1-2cf6-4cc2-8c22-0dc40aef3791'	System	30 Sep 2020 19:58:07
User entered '30 Sep 2020 12:58'	System	30 Sep 2020 19:58:07

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	24 Sep 2020 23:56:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-24T17:13:22', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '2c4ae2fb-77f0-4da8-b03d-1833403a09b7'	System	25 Sep 2020 00:13:53
User entered 'None (0)'	System	25 Sep 2020 00:13:53

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-24T17:13:28', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '2c4ae2fb-77f0-4da8-b03d-1833403a09b7'	System	25 Sep 2020 00:13:53
User entered 'None (0)'	System	25 Sep 2020 00:13:53

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-24T17:13:30', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '2c4ae2fb-77f0-4da8-b03d-1833403a09b7'	System	25 Sep 2020 00:13:53
User entered 'None (0)'	System	25 Sep 2020 00:13:53

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-24T17:13:33', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '2c4ae2fb-77f0-4da8-b03d-1833403a09b7'	System	25 Sep 2020 00:13:53
User entered 'None (0)'	System	25 Sep 2020 00:13:53

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-24T17:13:41', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '2c4ae2fb-77f0-4da8-b03d-1833403a09b7'	System	25 Sep 2020 00:13:53
User entered 'None (0)'	System	25 Sep 2020 00:13:53

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-24T17:13:43', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '2c4ae2fb-77f0-4da8-b03d-1833403a09b7'	System	25 Sep 2020 00:13:53
User entered 'None (0)'	System	25 Sep 2020 00:13:53

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-24T17:13:46', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '2c4ae2fb-77f0-4da8-b03d-1833403a09b7'	System	25 Sep 2020 00:13:53
User entered 'No (N)'	System	25 Sep 2020 00:13:53

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-24T17:13:49', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '2c4ae2fb-77f0-4da8-b03d-1833403a09b7'	System	25 Sep 2020 00:13:53
User entered '24 Sep 2020 17:13'	System	25 Sep 2020 00:13:53

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '24 Sep 2020 17:03'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '24 Sep 2020 19:33'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	24 Sep 2020 23:56:35
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T08:38:58', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '8087df6b-deb3-47bd-baf1-9f92e3269eda'	System	25 Sep 2020 15:39:14
User entered 'None (0)'	System	25 Sep 2020 15:39:14

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T08:39:00', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '8087df6b-deb3-47bd-baf1-9f92e3269eda'	System	25 Sep 2020 15:39:14
User entered 'None (0)'	System	25 Sep 2020 15:39:14

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T08:39:02', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '8087df6b-deb3-47bd-baf1-9f92e3269eda'	System	25 Sep 2020 15:39:14
User entered 'None (0)'	System	25 Sep 2020 15:39:14

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T08:39:03', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '8087df6b-deb3-47bd-baf1-9f92e3269eda'	System	25 Sep 2020 15:39:14
User entered 'None (0)'	System	25 Sep 2020 15:39:14

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T08:39:05', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '8087df6b-deb3-47bd-baf1-9f92e3269eda'	System	25 Sep 2020 15:39:14
User entered 'None (0)'	System	25 Sep 2020 15:39:14

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T08:39:06', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '8087df6b-deb3-47bd-baf1-9f92e3269eda'	System	25 Sep 2020 15:39:14
User entered 'None (0)'	System	25 Sep 2020 15:39:14

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T08:39:08', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '8087df6b-deb3-47bd-baf1-9f92e3269eda'	System	25 Sep 2020 15:39:14
User entered 'No (N)'	System	25 Sep 2020 15:39:14

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T08:39:11', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '8087df6b-deb3-47bd-baf1-9f92e3269eda'	System	25 Sep 2020 15:39:14
User entered '25 Sep 2020 08:39'	System	25 Sep 2020 15:39:14

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '24 Sep 2020 20:28'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	24 Sep 2020 23:56:35
User entered 'Day 2'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:43:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T22:36:36', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '99f8543a-0034-4ab1-a07d-8c84d9498d07'	System	26 Sep 2020 05:37:15
User entered 'No interference with activity (1)'	System	26 Sep 2020 05:37:15

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:43:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T22:36:40', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '99f8543a-0034-4ab1-a07d-8c84d9498d07'	System	26 Sep 2020 05:37:15
User entered 'None (0)'	System	26 Sep 2020 05:37:15

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:43:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T22:36:42', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '99f8543a-0034-4ab1-a07d-8c84d9498d07'	System	26 Sep 2020 05:37:15
User entered 'None (0)'	System	26 Sep 2020 05:37:15

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:43:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T22:37:03', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '99f8543a-0034-4ab1-a07d-8c84d9498d07'	System	26 Sep 2020 05:37:15
User entered 'None (0)'	System	26 Sep 2020 05:37:15

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:43:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T22:37:05', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '99f8543a-0034-4ab1-a07d-8c84d9498d07'	System	26 Sep 2020 05:37:15
User entered 'None (0)'	System	26 Sep 2020 05:37:15

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:43:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T22:37:07', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '99f8543a-0034-4ab1-a07d-8c84d9498d07'	System	26 Sep 2020 05:37:15
User entered 'None (0)'	System	26 Sep 2020 05:37:15

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T22:37:10', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '99f8543a-0034-4ab1-a07d-8c84d9498d07'	System	26 Sep 2020 05:37:15
User entered 'No (N)'	System	26 Sep 2020 05:37:15

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:43:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-25T22:37:12', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '99f8543a-0034-4ab1-a07d-8c84d9498d07'	System	26 Sep 2020 05:37:15
User entered '25 Sep 2020 22:37'	System	26 Sep 2020 05:37:15

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	24 Sep 2020 23:56:35
User entered 'Day 3'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:43:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-27T06:16:03', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '719ff22c-4b68-4295-b683-c91bdc806a'	System	27 Sep 2020 13:16:22
User entered 'No interference with activity (1)'	System	27 Sep 2020 13:16:22

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:43:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-27T06:16:07', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '719ff22c-4b68-4295-b683-c91bdc806a'	System	27 Sep 2020 13:16:22
User entered 'None (0)'	System	27 Sep 2020 13:16:22

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:43:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-27T06:16:10', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '719ff22c-4b68-4295-b683-c91bdc806a'	System	27 Sep 2020 13:16:22
User entered 'None (0)'	System	27 Sep 2020 13:16:22

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:43:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-27T06:16:13', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '719ff22c-4b68-4295-b683-c91bdc806a'	System	27 Sep 2020 13:16:22
User entered 'None (0)'	System	27 Sep 2020 13:16:22

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:43:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-27T06:16:14', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '719ff22c-4b68-4295-b683-c91bdc806a'	System	27 Sep 2020 13:16:22
User entered 'None (0)'	System	27 Sep 2020 13:16:22

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:43:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-27T06:16:16', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '719ff22c-4b68-4295-b683-c91bdc806a'	System	27 Sep 2020 13:16:22
User entered 'None (0)'	System	27 Sep 2020 13:16:22

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-27T06:16:18', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '719ff22c-4b68-4295-b683-c91bdc806a'	System	27 Sep 2020 13:16:22
User entered 'No (N)'	System	27 Sep 2020 13:16:22

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:43:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-27T06:16:20', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '719ff22c-4b68-4295-b683-c91bdc806a'	System	27 Sep 2020 13:16:22
User entered '27 Sep 2020 06:16'	System	27 Sep 2020 13:16:22

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	24 Sep 2020 23:56:35
User entered 'Day 4'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:43:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T04:53:28', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '806f1273-e3c3-4908-ab53-1839ebbf76ef'	System	28 Sep 2020 11:53:44
User entered 'None (0)'	System	28 Sep 2020 11:53:44

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:43:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T04:53:31', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '806f1273-e3c3-4908-ab53-1839ebbf76ef'	System	28 Sep 2020 11:53:44
User entered 'None (0)'	System	28 Sep 2020 11:53:44

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:43:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T04:53:33', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '806f1273-e3c3-4908-ab53-1839ebbf76ef'	System	28 Sep 2020 11:53:44
User entered 'None (0)'	System	28 Sep 2020 11:53:44

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:43:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T04:53:35', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '806f1273-e3c3-4908-ab53-1839ebbf76ef'	System	28 Sep 2020 11:53:44
User entered 'None (0)'	System	28 Sep 2020 11:53:44

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:43:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T04:53:37', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '806f1273-e3c3-4908-ab53-1839ebbf76ef'	System	28 Sep 2020 11:53:44
User entered 'None (0)'	System	28 Sep 2020 11:53:44

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:43:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T04:53:39', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '806f1273-e3c3-4908-ab53-1839ebbf76ef'	System	28 Sep 2020 11:53:44
User entered 'None (0)'	System	28 Sep 2020 11:53:44

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T04:53:41', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '806f1273-e3c3-4908-ab53-1839ebbf76ef'	System	28 Sep 2020 11:53:44
User entered 'No (N)'	System	28 Sep 2020 11:53:44

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:43:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T04:53:43', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '806f1273-e3c3-4908-ab53-1839ebbf76ef'	System	28 Sep 2020 11:53:44
User entered '28 Sep 2020 04:53'	System	28 Sep 2020 11:53:44

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	24 Sep 2020 23:56:35
User entered 'Day 5'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:43:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T22:58:38', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'b2d7d59a-2712-4b21-a5c9-14b41b4f2bd5'	System	29 Sep 2020 05:58:50
User entered 'None (0)'	System	29 Sep 2020 05:58:50

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:43:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T22:58:39', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'b2d7d59a-2712-4b21-a5c9-14b41b4f2bd5'	System	29 Sep 2020 05:58:50
User entered 'None (0)'	System	29 Sep 2020 05:58:50

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:43:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T22:58:41', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'b2d7d59a-2712-4b21-a5c9-14b41b4f2bd5'	System	29 Sep 2020 05:58:50
User entered 'None (0)'	System	29 Sep 2020 05:58:50

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:43:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T22:58:42', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'b2d7d59a-2712-4b21-a5c9-14b41b4f2bd5'	System	29 Sep 2020 05:58:50
User entered 'None (0)'	System	29 Sep 2020 05:58:50

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:43:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T22:58:43', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'b2d7d59a-2712-4b21-a5c9-14b41b4f2bd5'	System	29 Sep 2020 05:58:50
User entered 'None (0)'	System	29 Sep 2020 05:58:50

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:43:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T22:58:45', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'b2d7d59a-2712-4b21-a5c9-14b41b4f2bd5'	System	29 Sep 2020 05:58:50
User entered 'None (0)'	System	29 Sep 2020 05:58:50

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T22:58:46', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'b2d7d59a-2712-4b21-a5c9-14b41b4f2bd5'	System	29 Sep 2020 05:58:50
User entered 'No (N)'	System	29 Sep 2020 05:58:50

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:43:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-28T22:58:49', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'b2d7d59a-2712-4b21-a5c9-14b41b4f2bd5'	System	29 Sep 2020 05:58:50
User entered '28 Sep 2020 22:58'	System	29 Sep 2020 05:58:50

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	24 Sep 2020 23:56:35
User entered 'Day 6'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:43:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:43:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:43:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:43:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:43:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:43:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:43:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	24 Sep 2020 23:56:35
User entered 'Day 7'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:43:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-30T12:58:03', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '5e69bdb8-bfb1-46c2-894f-019287203e51' User entered 'None (0)'	System	30 Sep 2020 19:58:17
	System	30 Sep 2020 19:58:17

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:43:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-30T12:58:05', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '5e69bdb8-bfb1-46c2-894f-019287203e51'	System	30 Sep 2020 19:58:17
User entered 'None (0)'	System	30 Sep 2020 19:58:17

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:43:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-30T12:58:06', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '5e69bdb8-bfb1-46c2-894f-019287203e51'	System	30 Sep 2020 19:58:17
User entered 'None (0)'	System	30 Sep 2020 19:58:17

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:43:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-30T12:58:07', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '5e69bdb8-bfb1-46c2-894f-019287203e51'	System	30 Sep 2020 19:58:17
User entered 'None (0)'	System	30 Sep 2020 19:58:17

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:43:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-30T12:58:08', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '5e69bdb8-bfb1-46c2-894f-019287203e51'	System	30 Sep 2020 19:58:17
User entered 'None (0)'	System	30 Sep 2020 19:58:17

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:43:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-30T12:58:10', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '5e69bdb8-bfb1-46c2-894f-019287203e51'	System	30 Sep 2020 19:58:17
User entered 'None (0)'	System	30 Sep 2020 19:58:17

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-30T12:58:12', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '5e69bdb8-bfb1-46c2-894f-019287203e51'	System	30 Sep 2020 19:58:17
User entered 'No (N)'	System	30 Sep 2020 19:58:17

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:43:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-09-30T12:58:14', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '5e69bdb8-bfb1-46c2-894f-019287203e51'	System	30 Sep 2020 19:58:17
User entered '30 Sep 2020 12:58'	System	30 Sep 2020 19:58:17

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:43:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 23:56:35

US3462374

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:43:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 23:56:35

US3462374

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:08:36

US3462374

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '01 Oct 2020'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:08:36

US3462374

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:08:36

US3462374

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:08:36

US3462374

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:08:43

US3462374

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered '1'	System	08 Nov 2020 06:08:43

US3462374

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:09:04

US3462374

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '08 Oct 2020'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:09:04

US3462374

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:09:04

US3462374

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:09:04

US3462374

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:09:14

US3462374

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered '1'	System	08 Nov 2020 06:09:14

US3462374

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:09:38

US3462374

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered '15 Oct 2020'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:09:38

US3462374

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:09:38

US3462374

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:09:38

US3462374

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:08
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:09:44

US3462374

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered '1'	System	08 Nov 2020 06:09:44

US3462374

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:09:59

US3462374

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '29 Oct 2020'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:09:59

US3462374

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'Clinic (Clinic)'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:09:59

US3462374

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered 'VISIT3'	System	08 Nov 2020 06:09:59

US3462374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:10:09

US3462374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:10:09

US3462374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:10:09

US3462374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered empty.	System	08 Nov 2020 06:10:09

US3462374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:10:09

US3462374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:10:09

US3462374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:10:09

US3462374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:10:09

US3462374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered empty.	System	08 Nov 2020 06:10:09

US3462374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:10:09

US3462374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered empty.	System	08 Nov 2020 06:10:09

US3462374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:10:09

US3462374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered empty.	System	08 Nov 2020 06:10:09

US3462374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:10:09

US3462374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered empty.	System	08 Nov 2020 06:10:09

US3462374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15

US3462374

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15

US3462374

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:10:19

US3462374

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:10:19

US3462374

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:10:37

US3462374

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '29 Oct 2020'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:10:37

US3462374

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered '12:07'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:10:37

US3462374

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered '29 Oct 2020 12:07'	System	08 Nov 2020 06:10:37

US3462374

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	13 Feb 2021 02:00:15
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:10:44

US3462374

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered '1'	System	08 Nov 2020 06:10:44

US3462374

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered 'Day 64'	System	28 Aug 2020 00:25:58

US3462374

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-10-27T06:04:15', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '560ac66a-1fdc-407d-8e26-d3daecf8bb42'	System	27 Oct 2020 13:04:33
User entered 'No (N)'	System	27 Oct 2020 13:04:33

US3462374

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

Have you been exposed to someone with 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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-10-27T06:04:24', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '560ac66a-1fdc-407d-8e26-d3daecf8bb42'	System	27 Oct 2020 13:04:33
User entered 'No (N)'	System	27 Oct 2020 13:04:33

US3462374

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-10-27T06:04:28', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '560ac66a-1fdc-407d-8e26-d3daecf8bb42'	System	27 Oct 2020 13:04:33
User entered '27 Oct 2020 06:04:28'	System	27 Oct 2020 13:04:33

US3462374

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered '27 Oct 2020 00:01'	System	28 Aug 2020 00:25:58

US3462374

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered '31 Oct 2020 23:59'	System	28 Aug 2020 00:25:58

US3462374

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered 'Day 71'	System	28 Aug 2020 00:25:58

US3462374

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-11-03T11:38:42', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '267f369b-a2cc-40d8-a9a0-14e406ebd749'	System	03 Nov 2020 19:38:51
User entered 'No (N)'	System	03 Nov 2020 19:38:51

US3462374

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

Have you been exposed to someone with 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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-11-03T11:38:45', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '267f369b-a2cc-40d8-a9a0-14e406ebd749'	System	03 Nov 2020 19:38:51
User entered 'No (N)'	System	03 Nov 2020 19:38:51

US3462374

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-11-03T11:38:49', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '267f369b-a2cc-40d8-a9a0-14e406ebd749'	System	03 Nov 2020 19:38:51
User entered '03 Nov 2020 11:38:49'	System	03 Nov 2020 19:38:51

US3462374

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered '03 Nov 2020 00:01'	System	28 Aug 2020 00:25:58

US3462374

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered '07 Nov 2020 23:59'	System	28 Aug 2020 00:25:58

US3462374

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered 'Day 78'	System	28 Aug 2020 00:25:58

US3462374

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

[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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-11-10T18:13:09', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'c78ddce1-01c7-4dde-9fa7-e6a808284327'	System	11 Nov 2020 02:13:18
User entered 'No (N)'	System	11 Nov 2020 02:13:18

US3462374

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

Have you been exposed to someone with 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 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-11-10T18:13:13', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'c78ddce1-01c7-4dde-9fa7-e6a808284327'	System	11 Nov 2020 02:13:18
User entered 'No (N)'	System	11 Nov 2020 02:13:18

US3462374

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-11-10T18:13:16', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'c78ddce1-01c7-4dde-9fa7-e6a808284327'	System	11 Nov 2020 02:13:18
User entered '10 Nov 2020 18:13:16'	System	11 Nov 2020 02:13:18

US3462374

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered '10 Nov 2020 00:01'	System	28 Aug 2020 00:25:58

US3462374

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:45:16
Data entry locked.	System	28 Aug 2020 00:25:58
User entered '14 Nov 2020 23:59'	System	28 Aug 2020 00:25:58

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 19:34:19

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

[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 (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-11-24T04:18:16', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '5cef4e8b-8442-4779-91d6-fb90b959a3b3'	System	24 Nov 2020 12:18:33
User entered 'No (N)'	System	24 Nov 2020 12:18:33

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

Have you been exposed to someone with 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 (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-11-24T04:18:27', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '5cef4e8b-8442-4779-91d6-fb90b959a3b3'	System	24 Nov 2020 12:18:33
User entered 'No (N)'	System	24 Nov 2020 12:18:33

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-11-24T04:18:31', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '5cef4e8b-8442-4779-91d6-fb90b959a3b3' User entered '24 Nov 2020 04:18:31'	System	24 Nov 2020 12:18:33
	System	24 Nov 2020 12:18:33

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 19:34:19

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

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 (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-12-01T20:58:25', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '608b8d77-f403-46a4-96b1-f1e25fa6b3ea' User entered 'No (N)'	System	02 Dec 2020 04:58:38
	System	02 Dec 2020 04:58:38

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

Have you been exposed to someone with 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 (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-12-01T20:58:29', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '608b8d77-f403-46a4-96b1-f1e25fa6b3ea'	System	02 Dec 2020 04:58:38
User entered 'No (N)'	System	02 Dec 2020 04:58:38

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-12-01T20:58:32', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '608b8d77-f403-46a4-96b1-f1e25fa6b3ea' User entered '01 Dec 2020 20:58:32'	System	02 Dec 2020 04:58:38
	System	02 Dec 2020 04:58:38

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 19:34:19

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

[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 (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-12-05T12:21:34', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'af693e34-cdc-4697-839f-b6f70bde9972'	System	05 Dec 2020 20:21:42
User entered 'No (N)'	System	05 Dec 2020 20:21:42

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

Have you been exposed to someone with 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 (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-12-05T12:21:37', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'af693e34-cdc-4697-839f-b6f70bde9972'	System	05 Dec 2020 20:21:42
User entered 'No (N)'	System	05 Dec 2020 20:21:42

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-12-05T12:21:40', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'af693e34-cdc-4697-839f-b6f70bde9972'	System	05 Dec 2020 20:21:42
User entered '05 Dec 2020 12:21:40'	System	05 Dec 2020 20:21:42

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 19:34:19

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

[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 (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-12-12T10:24:53', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'cd3d8fc3-bed1-40ea-862b-09d1b316bd33'	System	12 Dec 2020 18:25:00
User entered 'No (N)'	System	12 Dec 2020 18:25:00

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

Have you been exposed to someone with 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 (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-12-12T10:24:56', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'cd3d8fc3-bed1-40ea-862b-09d1b316bd33'	System	12 Dec 2020 18:25:00
User entered 'No (N)'	System	12 Dec 2020 18:25:00

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-12-12T10:24:59', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'cd3d8fc3-bed1-40ea-862b-09d1b316bd33'	System	12 Dec 2020 18:25:00
User entered '12 Dec 2020 10:24:59'	System	12 Dec 2020 18:25:00

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 19:34:19

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

[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 (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-12-19T21:18:43', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '5b0de6eb-ab74-4f83-a09b-bc507a630010'	System	20 Dec 2020 05:18:53
User entered 'No (N)'	System	20 Dec 2020 05:18:53

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

Have you been exposed to someone with 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 (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-12-19T21:18:47', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '5b0de6eb-ab74-4f83-a09b-bc507a630010' User entered 'No (N)'	System	20 Dec 2020 05:18:53
	System	20 Dec 2020 05:18:53

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-12-19T21:18:50', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '5b0de6eb-ab74-4f83-a09b-bc507a630010'	System	20 Dec 2020 05:18:53
User entered '19 Dec 2020 21:18:50'	System	20 Dec 2020 05:18:53

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 19:34:19

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

[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 (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-12-26T00:04:20', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '5db354fa-a037-4622-9b4b-bb8e8d58ca4c'	System	26 Dec 2020 07:04:30
User entered 'No (N)'	System	26 Dec 2020 07:04:30

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

Have you been exposed to someone with 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 (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-12-26T00:04:23', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '5db354fa-a037-4622-9b4b-bb8e8d58ca4c'	System	26 Dec 2020 07:04:30
User entered 'No (N)'	System	26 Dec 2020 07:04:30

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2020-12-26T00:04:26', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '5db354fa-a037-4622-9b4b-bb8e8d58ca4c' User entered '26 Dec 2020 00:04:26'	System	26 Dec 2020 07:04:30
	System	26 Dec 2020 07:04:30

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 19:34:19

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

[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 (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2021-01-02T00:35:42', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '4f92f382-f26a-414e-b221-e9b5c242b4ed'	System	02 Jan 2021 08:36:35
User entered 'Yes (Y)'	System	02 Jan 2021 08:36:35

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

Have you been exposed to someone with 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 (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2021-01-02T00:35:45', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '4f92f382-f26a-414e-b221-e9b5c242b4ed'	System	02 Jan 2021 08:36:35
User entered 'Yes (Y)'	System	02 Jan 2021 08:36:35

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

Please 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 (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2021-01-02T00:35:52', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '4f92f382-f26a-414e-b221-e9b5c242b4ed'	System	02 Jan 2021 08:36:35
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Jan 2021 08:36:35

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

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 (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2021-01-02T00:35:56', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '4f92f382-f26a-414e-b221-e9b5c242b4ed'	System	02 Jan 2021 08:36:35
User entered 'Yes (Y)'	System	02 Jan 2021 08:36:35

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Fever \(Temperature  \$\geq\$  100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2021-01-02T00:36:15', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '4f92f382-f26a-414e-b221-e9b5c242b4ed'	System	02 Jan 2021 08:36:35
User entered '1'	System	02 Jan 2021 08:36:35

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2021-01-02T00:36:15', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '4f92f382-f26a-414e-b221-e9b5c242b4ed'	System	02 Jan 2021 08:36:35
User entered '1'	System	02 Jan 2021 08:36:35

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2021-01-02T00:36:15', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '4f92f382-f26a-414e-b221-e9b5c242b4ed'	System	02 Jan 2021 08:36:35
User entered '1'	System	02 Jan 2021 08:36:35

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2021-01-02T00:36:15', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '4f92f382-f26a-414e-b221-e9b5c242b4ed' User entered '0'	System	02 Jan 2021 08:36:35
	System	02 Jan 2021 08:36:35

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2021-01-02T00:36:15', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '4f92f382-f26a-414e-b221-e9b5c242b4ed'	System	02 Jan 2021 08:36:35
User entered '0'	System	02 Jan 2021 08:36:35

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2021-01-02T00:36:15', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '4f92f382-f26a-414e-b221-e9b5c242b4ed'	System	02 Jan 2021 08:36:35
User entered '0'	System	02 Jan 2021 08:36:35

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2021-01-02T00:36:15', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '4f92f382-f26a-414e-b221-e9b5c242b4ed'	System	02 Jan 2021 08:36:35
User entered '1'	System	02 Jan 2021 08:36:35

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2021-01-02T00:36:15', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '4f92f382-f26a-414e-b221-e9b5c242b4ed'	System	02 Jan 2021 08:36:35
User entered '0'	System	02 Jan 2021 08:36:35

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2021-01-02T00:36:15', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '4f92f382-f26a-414e-b221-e9b5c242b4ed'	System	02 Jan 2021 08:36:35
User entered '1'	System	02 Jan 2021 08:36:35

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2021-01-02T00:36:15', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '4f92f382-f26a-414e-b221-e9b5c242b4ed'	System	02 Jan 2021 08:36:35
User entered '0'	System	02 Jan 2021 08:36:35

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2021-01-02T00:36:15', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '4f92f382-f26a-414e-b221-e9b5c242b4ed'	System	02 Jan 2021 08:36:35
User entered '0'	System	02 Jan 2021 08:36:35

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2021-01-02T00:36:15', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '4f92f382-f26a-414e-b221-e9b5c242b4ed'	System	02 Jan 2021 08:36:35
User entered '1'	System	02 Jan 2021 08:36:35

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2021-01-02T00:36:15', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '4f92f382-f26a-414e-b221-e9b5c242b4ed' User entered '0'	System	02 Jan 2021 08:36:35
	System	02 Jan 2021 08:36:35

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2021-01-02T00:36:15', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '4f92f382-f26a-414e-b221-e9b5c242b4ed'	System	02 Jan 2021 08:36:35
User entered '0'	System	02 Jan 2021 08:36:35

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2021-01-02T00:36:15', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '4f92f382-f26a-414e-b221-e9b5c242b4ed'	System	02 Jan 2021 08:36:35
User entered '0'	System	02 Jan 2021 08:36:35

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2021-01-02T00:36:15', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '4f92f382-f26a-414e-b221-e9b5c242b4ed'	System	02 Jan 2021 08:36:35
User entered '0'	System	02 Jan 2021 08:36:35

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2021-01-02T00:36:15', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '4f92f382-f26a-414e-b221-e9b5c242b4ed'	System	02 Jan 2021 08:36:35
User entered '0'	System	02 Jan 2021 08:36:35

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

Please 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 (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2021-01-02T00:36:18', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '4f92f382-f26a-414e-b221-e9b5c242b4ed'	System	02 Jan 2021 08:36:35
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Jan 2021 08:36:35

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

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 (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2021-01-02T00:36:23', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '4f92f382-f26a-414e-b221-e9b5c242b4ed'	System	02 Jan 2021 08:36:35
User entered 'No (N)'	System	02 Jan 2021 08:36:35

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8A2BDD69-DFAC-4B0C-9378-538D1B78C58E)', Time: '2021-01-02T00:36:26', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '4f92f382-f26a-414e-b221-e9b5c242b4ed'	System	02 Jan 2021 08:36:35
User entered '02 Jan 2021 00:36:26'	System	02 Jan 2021 08:36:35

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 19:34:19

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 19:34:19

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 19:34:19

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

[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 (468D632D-440B-4D73-9696-0E5BE25D5238)', Time: '2021-03-13T22:20:35-08:00', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '6a2e2fe1-ebba-4c77-ab55-d49c00f34b2b'	System	14 Mar 2021 06:20:57
User entered 'No (N)'	System	14 Mar 2021 06:20:57

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

Have you been exposed to someone with 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 (468D632D-440B-4D73-9696-0E5BE25D5238)', Time: '2021-03-13T22:20:39-08:00', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '6a2e2fe1-ebba-4c77-ab55-d49c00f34b2b'	System	14 Mar 2021 06:20:57
User entered 'No (N)'	System	14 Mar 2021 06:20:57

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (468D632D-440B-4D73-9696-0E5BE25D5238)', Time: '2021-03-13T22:20:54-08:00', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '6a2e2fe1-ebba-4c77-ab55-d49c00f34b2b' User entered '13 Mar 2021 22:20:54'	System	14 Mar 2021 06:20:57
	System	14 Mar 2021 06:20:57

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 19:34:19

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

[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 (468D632D-440B-4D73-9696-0E5BE25D5238)', Time: '2021-03-21T04:58:59-07:00', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'c53ac6fb-f092-4583-bd87-302f6751ba7b'	System	21 Mar 2021 11:59:10
User entered 'No (N)'	System	21 Mar 2021 11:59:10

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

Have you been exposed to someone with 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 (468D632D-440B-4D73-9696-0E5BE25D5238)', Time: '2021-03-21T04:59:03-07:00', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'c53ac6fb-f092-4583-bd87-302f6751ba7b'	System	21 Mar 2021 11:59:10
User entered 'No (N)'	System	21 Mar 2021 11:59:10

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (468D632D-440B-4D73-9696-0E5BE25D5238)', Time: '2021-03-21T04:59:06-07:00', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'c53ac6fb-f092-4583-bd87-302f6751ba7b'	System	21 Mar 2021 11:59:10
User entered '21 Mar 2021 04:59:06'	System	21 Mar 2021 11:59:10

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 19:34:19

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

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 (468D632D-440B-4D73-9696-0E5BE25D5238)', Time: '2021-03-28T05:14:43-07:00', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'b367e2a6-eb07-4464-aa71-fc3b3d856505'	System	28 Mar 2021 12:14:52
User entered 'No (N)'	System	28 Mar 2021 12:14:52

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

Have you been exposed to someone with 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 (468D632D-440B-4D73-9696-0E5BE25D5238)', Time: '2021-03-28T05:14:45-07:00', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'b367e2a6-eb07-4464-aa71-fc3b3d856505'	System	28 Mar 2021 12:14:52
User entered 'No (N)'	System	28 Mar 2021 12:14:52

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (468D632D-440B-4D73-9696-0E5BE25D5238)', Time: '2021-03-28T05:14:48-07:00', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'b367e2a6-eb07-4464-aa71-fc3b3d856505'	System	28 Mar 2021 12:14:52
User entered '28 Mar 2021 05:14:48'	System	28 Mar 2021 12:14:52

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 19:34:19

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

[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 (468D632D-440B-4D73-9696-0E5BE25D5238)', Time: '2021-04-05T12:00:25-07:00', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'dd5f9240-dd5d-48cd-9786-59fe789a43d1'	System	05 Apr 2021 19:00:44
User entered 'No (N)'	System	05 Apr 2021 19:00:44

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

Have you been exposed to someone with 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 (468D632D-440B-4D73-9696-0E5BE25D5238)', Time: '2021-04-05T12:00:26-07:00', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'dd5f9240-dd5d-48cd-9786-59fe789a43d1'	System	05 Apr 2021 19:00:44
User entered 'No (N)'	System	05 Apr 2021 19:00:44

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (468D632D-440B-4D73-9696-0E5BE25D5238)', Time: '2021-04-05T12:00:29-07:00', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'dd5f9240-dd5d-48cd-9786-59fe789a43d1'	System	05 Apr 2021 19:00:44
User entered '05 Apr 2021 12:00:29'	System	05 Apr 2021 19:00:44

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 19:34:19

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 19:34:19

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

[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 (6D45CE83-AFC1-41B7-97D6-F916CDA578A2)', Time: '2021-04-26T17:08:13-07:00', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'fec672bb-db09-499a-bccf-41e54c110ee0'	System	27 Apr 2021 00:08:28
User entered 'No (N)'	System	27 Apr 2021 00:08:28

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

Have you been exposed to someone with 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 (6D45CE83-AFC1-41B7-97D6-F916CDA578A2)', Time: '2021-04-26T17:08:19-07:00', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'fec672bb-db09-499a-bccf-41e54c110ee0'	System	27 Apr 2021 00:08:28
User entered 'No (N)'	System	27 Apr 2021 00:08:28

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D45CE83-AFC1-41B7-97D6-F916CDA578A2)', Time: '2021-04-26T17:08:22-07:00', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'fec672bb-db09-499a-bccf-41e54c110ee0'	System	27 Apr 2021 00:08:28
User entered '26 Apr 2021 17:08:22'	System	27 Apr 2021 00:08:28

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 19:34:19

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

[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 (6D45CE83-AFC1-41B7-97D6-F916CDA578A2)', Time: '2021-05-02T07:42:00-07:00', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '33082048-9cfc-4053-b877-32ad1a42f8fd'	System	02 May 2021 14:42:12
User entered 'No (N)'	System	02 May 2021 14:42:12

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

Have you been exposed to someone with 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 (6D45CE83-AFC1-41B7-97D6-F916CDA578A2)', Time: '2021-05-02T07:42:02-07:00', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '33082048-9cfc-4053-b877-32ad1a42f8fd'	System	02 May 2021 14:42:12
User entered 'No (N)'	System	02 May 2021 14:42:12

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6D45CE83-AFC1-41B7-97D6-F916CDA578A2)', Time: '2021-05-02T07:42:05-07:00', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: '33082048-9cfc-4053-b877-32ad1a42f8fd'	System	02 May 2021 14:42:12
User entered '02 May 2021 07:42:05'	System	02 May 2021 14:42:12

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 19:34:19

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 19:34:19

US3462374

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:43:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '29 Oct 2022 00:01'	System	19 Nov 2020 19:34:19

**US3462374**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:43:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:34:19
Amendment Manager: User entered '02 Nov 2022 23:59'	System	19 Nov 2020 19:34:19

US3462374

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:43:38

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 07:27:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (468D632D-440B-4D73-9696-0E5BE25D5238)', Time: '2021-03-11T16:55:35-08:00', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'b41a2a10-0133-4ff2-8312-a49e0bc813dd'	System	12 Mar 2021 00:55:41
User entered 'No (N)'	System	12 Mar 2021 00:55:41

US3462374

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:43:38

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:27:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (468D632D-440B-4D73-9696-0E5BE25D5238)', Time: '2021-03-11T16:55:39-08:00', User OID: 'PatientReportedOutcome (US3462374)', ODM File OID: 'b41a2a10-0133-4ff2-8312-a49e0bc813dd'	System	12 Mar 2021 00:55:41
User entered '11 Mar 2021 16:55:39'	System	12 Mar 2021 00:55:41

US3462374

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:15

US3462374

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered '19 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:15

US3462374

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:15

US3462374

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:15

US3462374

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:22

US3462374

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:52:15
User entered '1'	System	19 Nov 2020 21:50:22

US3462374

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:51:47

US3462374

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered '22 Dec 2020'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:51:47

US3462374

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:51:47

US3462374

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:51:47

US3462374

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:51:53

US3462374

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User entered '1'	System	28 Jan 2021 18:51:53

US3462374

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	28 Jan 2021 18:52:33
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	28 Jan 2021 18:52:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Jan 2021 18:52:26

US3462374

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:52:26

US3462374

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:52:33
User entered empty.		28 Jan 2021 18:52:26

US3462374

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:52:26

US3462374

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 18:52:38

US3462374

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User entered '1'	System	28 Jan 2021 18:52:38

US3462374

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:12

US3462374

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:12

US3462374

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:12

US3462374

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:12

US3462374

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:17

US3462374

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User entered '1'	System	25 Feb 2021 21:42:17

US3462374

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:59:47

US3462374

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '11 Mar 2021'	(b) (4) (p) (4), (b) (6)	12 Mar 2021 16:59:47

US3462374

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[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 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered 'Clinic (Clinic)'	(b) (4) (u) (4), (b) (6)	12 Mar 2021 16:59:47

US3462374

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User entered 'VISIT4'	System	12 Mar 2021 16:59:47

US3462374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User closed query 'Per CDM re-query: Response noted; Visit 4 and PDV/OL-D1 occurred on same day. However Vital signs form doesn't match at both the visits. Per sponsor if the Vital signs assessed it has to be recorded at both the visits. Please update as appropriate. ' (Site from DM). User signature succeeded.	(b) (4)	01 Apr 2021 04:55:55
	Gregg Lucksinger (b) (4)	31 Mar 2021 21:39:22
Query 'Per CDM re-query: Response noted; Visit 4 and PDV/OL-D1 occurred on same day. However Vital signs form doesn't match at both the visits. Per sponsor if the Vital signs assessed it has to be recorded at both the visits. Please update as appropriate. ' answered with 'Updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:14
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 19:34:30
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 19:34:30
User closed query 'Per CDM: Visit 4 Day 209 and Participant Decision Visit/OL-D1 are both dated 11Mar2021, however, 'Were vital signs assessed?' is NO at this visit but at OL-D1 'Were vital signs assessed?' is YES and data is present. Please review and update this page as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 11:25:26
User opened query 'Per CDM re-query: Response noted; Visit 4 and PDV/OL-D1 occurred on same day. However Vital signs form doesn't match at both the visits. Per sponsor if the Vital signs assessed it has to be recorded at both the visits. Please update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 11:25:24

US3462374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

Were vital signs assessed?

Audit	User	Time (GMT)
Query 'Per CDM: Visit 4 Day 209 and Participant Decision Visit/OL-D1 are both dated 11Mar2021, however, 'Were vital signs assessed?' is NO at this visit but at OL-D1 'Were vital signs assessed?' is YES and data is present. Please review and update this page as appropriate.' answered with 'Vitals were assessed for OL-D1, but since patient had no AEs it was unnecessary to record vitals for Visit 4. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 15:39:30
User opened query 'Per CDM: Visit 4 Day 209 and Participant Decision Visit/OL-D1 are both dated 11Mar2021, however, 'Were vital signs assessed?' is NO at this visit but at OL-D1 'Were vital signs assessed?' is YES and data is present. Please review and update this page as appropriate.' (Site from DM). User signature succeeded.		30 Mar 2021 12:54:00
	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:52:59

US3462374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:39:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	31 Mar 2021 19:35:08
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 19:35:08
User entered '11 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 19:35:08
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Mar 2021 19:34:30
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:21
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:52:59

US3462374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:39:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	31 Mar 2021 19:35:08
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	31 Mar 2021 19:35:08
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 19:35:08
User entered '15:46' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 19:35:08
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Mar 2021 19:34:30
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:21
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:52:59

US3462374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User entered '11 Mar 2021 15:46'	System	31 Mar 2021 19:35:08
User entered empty.	System	29 Mar 2021 20:52:59

US3462374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:39:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	31 Mar 2021 19:35:08
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	31 Mar 2021 19:35:08
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 19:35:08
User entered '98.5' F reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 19:35:08
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Mar 2021 19:34:30
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:21
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:52:59

US3462374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	06 Apr 2021 14:32:13
User closed query 'Per CDM: Thank you for updating this form. However the route of measurement is Other-tympanic on this form which doesn't match with the route Oral at PDV/OL-D1 visit. Please review the response and update the appropriate route at both the visits. Thank you. ' (Site from DM). Query 'Per CDM: Thank you for updating this form. However the route of measurement is Other-tympanic on this form which doesn't match with the route Oral at PDV/OL-D1 visit. Please review the response and update the appropriate route at both the visits. Thank you. ' answered with 'Route of measurement is Tympanic. OL-1 ECRF updated.' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 12:16:10
User closed query 'Route of measurement is not Other, however, specify is provided. Please correct.' (Site from System).	System	05 Apr 2021 20:25:22
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 20:25:22
User opened query 'Route of measurement is not Other, however, specify is provided. Please correct.' (Site from System).	System	05 Apr 2021 20:23:39
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 20:23:39
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 20:23:39
User opened query 'Per CDM: Thank you for updating this form. However the route of measurement is Other-tympanic on this form which doesn't match with the route Oral at PDV/OL-D1 visit. Please review the response and update the appropriate route at both the visits. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 04:55:50
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:39:22

US3462374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Route of measurement](#)

Audit	User	Time (GMT)
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 19:35:08
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 19:35:08
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:21
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:52:59

US3462374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:39:22
Signature has been broken.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:08
User entered 'Tympanic' reason for change: Data Entry Error		31 Mar 2021 19:35:08
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:21
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:52:59

US3462374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:39:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	31 Mar 2021 19:35:08
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	31 Mar 2021 19:35:08
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 19:35:08
User entered '62' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 19:35:08
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Mar 2021 19:34:30
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:21
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:52:59

US3462374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User entered 'bpm'	System	31 Mar 2021 19:35:08
User entered empty.	System	29 Mar 2021 20:52:59

US3462374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:39:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	31 Mar 2021 19:35:08
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	31 Mar 2021 19:35:08
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 19:35:08
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 19:35:08
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Mar 2021 19:34:30
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:21
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:52:59

US3462374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User entered 'breaths/min'	System	31 Mar 2021 19:35:08
User entered empty.	System	29 Mar 2021 20:52:59

US3462374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:39:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	31 Mar 2021 19:35:08
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	31 Mar 2021 19:35:08
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 19:35:08
User entered '103' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 19:35:08
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Mar 2021 19:34:30
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:21
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:52:59

US3462374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User entered 'mmHg'	System	31 Mar 2021 19:35:08
User entered empty.	System	29 Mar 2021 20:52:59

US3462374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:39:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	31 Mar 2021 19:35:08
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	31 Mar 2021 19:35:08
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 19:35:08
User entered '70' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 19:35:08
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Mar 2021 19:34:30
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:21
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:52:59

US3462374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User entered 'mmHg'	System	31 Mar 2021 19:35:08
User entered empty.	System	29 Mar 2021 20:52:59

US3462374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33

US3462374

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33

US3462374

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered 'No (N)'	(b) (4) (p) (4), (b) (6)	12 Mar 2021 16:59:54

US3462374

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:59:54

US3462374

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered 'Yes (Y)'	(b) (4) (o) (4), (b) (6)	12 Mar 2021 17:00:06

US3462374

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 17:00:06

US3462374

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '15:27'	(b) (4) (p) (4), (b) (6)	12 Mar 2021 17:00:06

**US3462374**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:43:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User entered '11 Mar 2021 15:27'	System	12 Mar 2021 17:00:06

US3462374

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered 'Yes (Y)'	(b) (4) (p) (4), (b) (6)	12 Mar 2021 17:00:10

US3462374

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 08:43:33
User entered '1'	System	12 Mar 2021 17:00:10

US3462374

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	26 Apr 2021 22:32:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 21:39:12

US3462374

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	26 Apr 2021 22:32:15
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 21:39:12

US3462374

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	26 Apr 2021 22:32:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 21:39:12

US3462374

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	26 Apr 2021 22:32:15
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	26 Apr 2021 21:39:12

US3462374

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	26 Apr 2021 22:32:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 21:39:17

US3462374

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Continuing Flag](#)

---

Audit	User	Time (GMT)
User entered '1'	System	26 Apr 2021 21:39:17

---

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:43:38

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:40
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:54:25
User entered '01 Jan 2021'		07 Jan 2021 20:32:53

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:43:38

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:40
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:54:25
User entered '20:00'		07 Jan 2021 20:32:53

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:43:38

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:40
User entered '01 Jan 2021 20:00'	System	07 Jan 2021 20:32:53

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:43:38

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:40
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:54:25
User entered 'Safety Call (Safety Call)'		07 Jan 2021 20:32:53

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:43:38

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:40
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 19:54:25
User entered 'Yes (Y)'		07 Jan 2021 20:32:53

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 20:33:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User closed query 'Per source, please complete Symptom Log Lines up to (17Jan2021). ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:02
Query 'Per source, please complete Symptom Log Lines up to (17Jan2021). ' answered with 'Updated' (Site from CRA).		01 Feb 2021 20:50:21
DataPoint Verified.		28 Jan 2021 20:02:05
User opened query 'Per source, please complete Symptom Log Lines up to (17Jan2021). ' (Site from CRA).		28 Jan 2021 19:57:32
Query 'Per source, please complete Symptom Log Lines up to Day 14 (17Jan2021).' canceled (Site from CRA).		28 Jan 2021 19:57:16
User opened query 'Per source, please complete Symptom Log Lines up to Day 14 (17Jan2021).' (Site from CRA).		28 Jan 2021 19:55:52
User entered '01 Jan 2021'		07 Jan 2021 20:33:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:02:05
User entered '0' reason for change: Data Entry Error		07 Jan 2021 20:35:26
User entered '1'		07 Jan 2021 20:33:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
DataPoint Un-verified.		01 Feb 2021 21:26:14
User entered missing code ND - Not Done; reason for change Data Entry Error		01 Feb 2021 21:26:14
DataPoint Verified.		28 Jan 2021 20:02:05
User entered empty.		07 Jan 2021 20:33:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User entered '%'	System	01 Feb 2021 21:26:14
User entered empty.	System	07 Jan 2021 20:33:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:02:05
User entered '101' F reason for change: Data Entry Error		07 Jan 2021 20:35:26
User entered empty.		07 Jan 2021 20:33:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:02:05
User entered 'None (None)' reason for change: Data Entry Error		07 Jan 2021 20:35:26
User entered empty.		07 Jan 2021 20:33:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:02:05
User entered 'Mild (Mild)' reason for change: Data Entry Error		07 Jan 2021 20:35:26
User entered empty.		07 Jan 2021 20:33:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:02:05
User entered 'None (None)' reason for change: Data Entry Error		07 Jan 2021 20:35:26
User entered empty.		07 Jan 2021 20:33:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:02:05
User entered 'None (None)' reason for change: Data Entry Error		07 Jan 2021 20:35:26
User entered empty.		07 Jan 2021 20:33:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:02:05
User entered 'None (None)' reason for change: Data Entry Error		07 Jan 2021 20:35:26
User entered empty.		07 Jan 2021 20:33:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:02:05
User entered 'Mild (Mild)' reason for change: Data Entry Error		07 Jan 2021 20:35:26
User entered empty.		07 Jan 2021 20:33:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:02:05
User entered 'None (None)' reason for change: Data Entry Error		07 Jan 2021 20:35:26
User entered empty.		07 Jan 2021 20:33:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:02:05
User entered 'Mild (Mild)' reason for change: Data Entry Error		07 Jan 2021 20:35:26
User entered empty.		07 Jan 2021 20:33:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:02:05
User entered 'None (None)' reason for change: Data Entry Error		07 Jan 2021 20:35:26
User entered empty.		07 Jan 2021 20:33:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:02:05
User entered 'None (None)' reason for change: Data Entry Error		07 Jan 2021 20:35:26
User entered empty.		07 Jan 2021 20:33:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:02:05
User entered 'None (None)' reason for change: Data Entry Error		07 Jan 2021 20:35:26
User entered empty.		07 Jan 2021 20:33:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:02:05
User entered 'None (None)' reason for change: Data Entry Error		07 Jan 2021 20:35:26
User entered empty.		07 Jan 2021 20:33:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:02:05
User entered 'None (None)' reason for change: Data Entry Error		07 Jan 2021 20:35:26
User entered empty.		07 Jan 2021 20:33:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:02:05
User entered 'None (None)' reason for change: Data Entry Error		07 Jan 2021 20:35:26
User entered empty.		07 Jan 2021 20:33:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:11
User closed query 'Per source, diarrhea did not start until 02Jan2021. Please clarify. ' (Site from CRA).		09 Feb 2021 19:44:09
Query 'Per source, diarrhea did not start until 02Jan2021. Please clarify. ' answered with 'Corrected' (Site from CRA).		01 Feb 2021 20:51:21
DataPoint Un-verified.		01 Feb 2021 20:51:15
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 20:51:15
DataPoint Verified.		28 Jan 2021 20:02:05
User opened query 'Per source, diarrhea did not start until 02Jan2021. Please clarify. ' (Site from CRA).		28 Jan 2021 19:58:32
User entered 'Mild (Mild)' reason for change: Data Entry Error		07 Jan 2021 20:35:26
User entered empty.		07 Jan 2021 20:33:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:43:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:02:05
User entered 'Mild (Mild)' reason for change: Data Entry Error		07 Jan 2021 20:35:26
User entered empty.		07 Jan 2021 20:33:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 20:37:01

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:00:43
User entered '02 Jan 2021'		07 Jan 2021 20:37:01

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:02:05
User entered '0'		07 Jan 2021 20:37:01

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:43:48
DataPoint Un-verified.		01 Feb 2021 21:26:14
User entered missing code ND - Not Done; reason fo change Data Entry Error		01 Feb 2021 21:26:14
DataPoint Verified.		28 Jan 2021 20:02:05
User entered empty.		07 Jan 2021 20:37:01

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User entered '%'	System	01 Feb 2021 21:26:14
User entered empty.	System	07 Jan 2021 20:37:01

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:46
User entered '101' F		07 Jan 2021 20:37:01

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:48
User entered 'None (None)'		07 Jan 2021 20:37:01

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:49
User entered 'Mild (Mild)'		07 Jan 2021 20:37:01

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User closed query 'For all blank entries, please indicate 'None' if no symptoms reported.' (Site from CRA).		09 Feb 2021 19:43:54
Query 'For all blank entries, please indicate 'None' if no symptoms reported.' answered with 'Corrected' (Site from CRA).		01 Feb 2021 20:51:05
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 20:50:58
DataPoint Un-verified.		28 Jan 2021 20:02:22
DataPoint Verified.		28 Jan 2021 20:02:19
DataPoint Un-verified.		28 Jan 2021 20:02:15
DataPoint Verified.		28 Jan 2021 20:02:05
User opened query 'For all blank entries, please indicate 'None' if no symptoms reported.' (Site from CRA).		28 Jan 2021 20:00:36
Query 'Please indicate 'None' if no symptoms reported. ' canceled (Site from CRA).		28 Jan 2021 19:59:55
User opened query 'Please indicate 'None' if no symptoms reported. ' (Site from CRA).		28 Jan 2021 19:59:50
User entered empty.		07 Jan 2021 20:37:01

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 20:50:58
DataPoint Un-verified.		28 Jan 2021 20:02:23
DataPoint Verified.		28 Jan 2021 20:02:05
User entered empty.		07 Jan 2021 20:37:01

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 20:50:58
DataPoint Un-verified.		28 Jan 2021 20:02:25
DataPoint Verified.		28 Jan 2021 20:02:05
User entered empty.		07 Jan 2021 20:37:01

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:00:53
User entered 'Mild (Mild)'		07 Jan 2021 20:37:01

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 20:50:58
DataPoint Un-verified.		28 Jan 2021 20:02:27
DataPoint Verified.		28 Jan 2021 20:02:05
User entered empty.		07 Jan 2021 20:37:01

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:55
User entered 'Mild (Mild)'		07 Jan 2021 20:37:01

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 20:50:58
DataPoint Un-verified.		28 Jan 2021 20:02:29
DataPoint Verified.		28 Jan 2021 20:02:05
User entered empty.		07 Jan 2021 20:37:01

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 20:50:58
DataPoint Un-verified.		28 Jan 2021 20:02:31
DataPoint Verified.		28 Jan 2021 20:02:05
User entered empty.		07 Jan 2021 20:37:01

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 20:50:58
DataPoint Un-verified.		28 Jan 2021 20:02:32
DataPoint Verified.		28 Jan 2021 20:02:05
User entered empty.		07 Jan 2021 20:37:01

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 20:50:58
DataPoint Un-verified.		28 Jan 2021 20:02:33
DataPoint Verified.		28 Jan 2021 20:02:05
User entered empty.		07 Jan 2021 20:37:01

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 20:50:58
DataPoint Un-verified.		28 Jan 2021 20:02:35
DataPoint Verified.		28 Jan 2021 20:02:05
User entered empty.		07 Jan 2021 20:37:01

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 20:50:58
DataPoint Un-verified.		28 Jan 2021 20:02:36
DataPoint Verified.		28 Jan 2021 20:02:05
User entered empty.		07 Jan 2021 20:37:01

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:57
User entered 'Mild (Mild)'		07 Jan 2021 20:37:01

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:43:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:00:59
User entered 'Mild (Mild)'		07 Jan 2021 20:37:01

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 20:37:25

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User closed query 'Per ETRTR: Please add Symptom log lines after 03Jan21 as required. Data entry in this page is expected every 24 Hrs, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:43:28
Query 'Per ETRTR: Please add Symptom log lines after 03Jan21 as required. Data entry in this page is expected every 24 Hrs, thanks.' answered with 'updated' (Site from CRA).		01 Feb 2021 20:51:36
DataPoint Verified.		28 Jan 2021 20:02:05
User opened query 'Per ETRTR: Please add Symptom log lines after 03Jan21 as required. Data entry in this page is expected every 24 Hrs, thanks.' (Site from CRA).		26 Jan 2021 20:45:23
User entered '03 Jan 2021'		07 Jan 2021 20:37:25

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:02:05
User entered '0'		07 Jan 2021 20:37:25

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
DataPoint Un-verified.		01 Feb 2021 20:53:22
User entered missing code ND - Not Done; reason for change Data Entry Error		01 Feb 2021 20:53:22
DataPoint Verified.		28 Jan 2021 20:02:05
User entered empty.		07 Jan 2021 20:37:25

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User entered '%'	System	01 Feb 2021 20:53:22
User entered empty.	System	07 Jan 2021 20:37:25

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Feb 2021 20:53:28
User entered '100.3' F reason for change: Data Entry Error	(b) (4), (b) (6)	01 Feb 2021 20:53:28
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Feb 2021 20:53:22
DataPoint Un-verified.	(b) (4), (b) (6)	01 Feb 2021 20:53:22
User entered '100.3' (non-conformant).	(b) (4), (b) (6)	01 Feb 2021 20:53:22
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:02:05
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 20:37:25

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User closed query 'For all blank entries, please indicate 'None' if no symptoms reported.' (Site from CRA).		09 Feb 2021 19:43:36
Query 'For all blank entries, please indicate 'None' if no symptoms reported.' answered with 'Corrected' (Site from CRA).		01 Feb 2021 20:53:36
DataPoint Un-verified.		01 Feb 2021 20:53:22
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 20:53:22
User opened query 'For all blank entries, please indicate 'None' if no symptoms reported.' (Site from CRA).		28 Jan 2021 20:02:47
DataPoint Verified.		28 Jan 2021 20:02:05
User entered empty.		07 Jan 2021 20:37:25

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
DataPoint Un-verified.		01 Feb 2021 20:53:22
User entered 'Mild (Mild)' reason for change: Data Entry Error		01 Feb 2021 20:53:22
DataPoint Verified.		28 Jan 2021 20:02:05
User entered empty.		07 Jan 2021 20:37:25

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
DataPoint Un-verified.		01 Feb 2021 20:53:22
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 20:53:22
DataPoint Verified.		28 Jan 2021 20:02:05
User entered empty.		07 Jan 2021 20:37:25

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
DataPoint Un-verified.		01 Feb 2021 20:53:22
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 20:53:22
DataPoint Verified.		28 Jan 2021 20:02:05
User entered empty.		07 Jan 2021 20:37:25

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
DataPoint Un-verified.		01 Feb 2021 20:53:22
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 20:53:22
DataPoint Verified.		28 Jan 2021 20:02:05
User entered empty.		07 Jan 2021 20:37:25

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:38

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
DataPoint Un-verified.		01 Feb 2021 20:53:22
User entered 'Mild (Mild)' reason for change: Data Entry Error		01 Feb 2021 20:53:22
DataPoint Verified.		28 Jan 2021 20:02:05
User entered empty.		07 Jan 2021 20:37:25

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
DataPoint Un-verified.		01 Feb 2021 20:53:22
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 20:53:22
DataPoint Verified.		28 Jan 2021 20:02:05
User entered empty.		07 Jan 2021 20:37:25

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
DataPoint Un-verified.		01 Feb 2021 20:53:22
User entered 'Mild (Mild)' reason for change: Data Entry Error		01 Feb 2021 20:53:22
DataPoint Verified.		28 Jan 2021 20:02:05
User entered empty.		07 Jan 2021 20:37:25

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
DataPoint Un-verified.		01 Feb 2021 20:53:22
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 20:53:22
DataPoint Verified.		28 Jan 2021 20:02:05
User entered empty.		07 Jan 2021 20:37:25

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
DataPoint Un-verified.		01 Feb 2021 20:53:22
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 20:53:22
DataPoint Verified.		28 Jan 2021 20:02:05
User entered empty.		07 Jan 2021 20:37:25

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
DataPoint Un-verified.		01 Feb 2021 20:53:22
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 20:53:22
DataPoint Verified.		28 Jan 2021 20:02:05
User entered empty.		07 Jan 2021 20:37:25

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
DataPoint Un-verified.		01 Feb 2021 20:53:22
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 20:53:22
DataPoint Verified.		28 Jan 2021 20:02:05
User entered empty.		07 Jan 2021 20:37:25

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
DataPoint Un-verified.		01 Feb 2021 20:53:22
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 20:53:22
DataPoint Verified.		28 Jan 2021 20:02:05
User entered empty.		07 Jan 2021 20:37:25

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
DataPoint Un-verified.		01 Feb 2021 20:53:22
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 20:53:22
DataPoint Verified.		28 Jan 2021 20:02:05
User entered empty.		07 Jan 2021 20:37:25

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
DataPoint Un-verified.		01 Feb 2021 20:53:22
User entered 'Mild (Mild)' reason for change: Data Entry Error		01 Feb 2021 20:53:22
DataPoint Verified.		28 Jan 2021 20:02:05
User entered empty.		07 Jan 2021 20:37:25

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:43:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
DataPoint Un-verified.		01 Feb 2021 20:53:22
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 20:53:22
DataPoint Verified.		28 Jan 2021 20:02:05
User entered empty.		07 Jan 2021 20:37:25

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 20:38:42

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '04 Jan 2021' reason for change: Data Entry Error		01 Feb 2021 21:26:49
User entered '05 Jan 2021'		01 Feb 2021 20:38:42

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '0'		01 Feb 2021 20:38:42

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '99' reason for change: Data Entry Error		01 Feb 2021 20:40:00
User entered empty.		01 Feb 2021 20:38:42

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User entered '%'	System	01 Feb 2021 20:40:00
User entered empty.	System	01 Feb 2021 20:38:42

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '97.3' F reason for change: Data Entry Error		01 Feb 2021 20:40:00
User entered empty.		01 Feb 2021 20:38:42

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 21:30:15
User entered empty.		01 Feb 2021 20:38:42

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Mild (Mild)' reason for change: Data Entry Error		01 Feb 2021 20:40:00
User entered empty.		01 Feb 2021 20:38:42

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 21:30:15
User entered empty.		01 Feb 2021 20:38:42

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 21:30:15
User entered empty.		01 Feb 2021 20:38:42

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 21:30:15
User entered empty.		01 Feb 2021 20:38:42

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Moderate (Moderate)' reason for change: Data Entry Error		01 Feb 2021 21:30:15
User entered 'Mild (Mild)' reason for change: Data Entry Error		01 Feb 2021 20:40:00
User entered empty.		01 Feb 2021 20:38:42

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Moderate (Moderate)' reason for change: Data Entry Error		01 Feb 2021 21:30:15
User entered empty.		01 Feb 2021 20:38:42

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Mild (Mild)' reason for change: Data Entry Error		01 Feb 2021 21:30:15
User entered empty.		01 Feb 2021 20:38:42

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Moderate (Moderate)' reason for change: Data Entry Error		01 Feb 2021 21:30:15
User entered empty.		01 Feb 2021 20:38:42

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Moderate (Moderate)' reason for change: Data Entry Error		01 Feb 2021 21:30:15
User entered empty.		01 Feb 2021 20:38:42

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 21:30:15
User entered empty.		01 Feb 2021 20:38:42

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 21:31:09
User entered empty.		01 Feb 2021 20:38:42

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 21:31:09
User entered empty.		01 Feb 2021 20:38:42

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 21:31:09
User entered empty.		01 Feb 2021 20:38:42

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Mild (Mild)' reason for change: Data Entry Error		01 Feb 2021 20:40:00
User entered empty.		01 Feb 2021 20:38:42

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:43:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 21:31:09
User entered empty.		01 Feb 2021 20:38:42

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Feb 2021 20:50:11
User entered empty.		01 Feb 2021 20:40:00

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '05 Jan 2021' reason for change: Data Entry Error		01 Feb 2021 21:26:49
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Feb 2021 20:50:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Feb 2021 20:50:11
User entered '06 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Feb 2021 20:50:11
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Feb 2021 20:40:00
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 20:40:00

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '0'		01 Feb 2021 20:40:00

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '99' reason for change: Data Entry Error		01 Feb 2021 20:50:11
User entered empty.		01 Feb 2021 20:40:00

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User entered '%'	System	01 Feb 2021 20:50:11
User entered empty.	System	01 Feb 2021 20:40:00

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '97.3' F		01 Feb 2021 20:40:00

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 21:30:15
User entered empty.		01 Feb 2021 20:40:00

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Mild (Mild)'		01 Feb 2021 20:40:00

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 21:30:15
User entered empty.		01 Feb 2021 20:40:00

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 21:30:15
User entered empty.		01 Feb 2021 20:40:00

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 21:30:15
User entered empty.		01 Feb 2021 20:40:00

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Moderate (Moderate)' reason for change: Data Entry Error		01 Feb 2021 21:30:15
User entered 'Mild (Mild)'		01 Feb 2021 20:40:00

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Moderate (Moderate)' reason for change: Data Entry Error		01 Feb 2021 21:30:15
User entered empty.		01 Feb 2021 20:40:00

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Mild (Mild)' reason for change: Data Entry Error		01 Feb 2021 21:30:15
User entered empty.		01 Feb 2021 20:40:00

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Moderate (Moderate)' reason for change: Data Entry Error		01 Feb 2021 21:30:15
User entered empty.		01 Feb 2021 20:40:00

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Moderate (Moderate)' reason for change: Data Entry Error		01 Feb 2021 21:30:15
User entered empty.		01 Feb 2021 20:40:00

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 21:30:15
User entered empty.		01 Feb 2021 20:40:00

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 21:31:09
User entered empty.		01 Feb 2021 20:40:00

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 21:31:09
User entered empty.		01 Feb 2021 20:40:00

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 21:31:09
User entered empty.		01 Feb 2021 20:40:00

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 21:31:09
User entered empty.		01 Feb 2021 20:40:00

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:43:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 21:31:09
User entered empty.		01 Feb 2021 20:40:00

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Feb 2021 22:18:07
User entered empty.		01 Feb 2021 21:30:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Feb 2021 21:32:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Feb 2021 21:32:52
User entered '06 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Feb 2021 21:32:52
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Feb 2021 21:30:15
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 21:30:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '0'		01 Feb 2021 21:30:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '100' reason for change: Data Entry Error		01 Feb 2021 21:32:52
User entered empty.		01 Feb 2021 21:30:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User entered '%'	System	01 Feb 2021 21:32:52
User entered empty.	System	01 Feb 2021 21:30:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '97.3' F reason for change: Data Entry Error		01 Feb 2021 21:32:52
User entered empty.		01 Feb 2021 21:30:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 22:18:24
User entered empty.		01 Feb 2021 21:30:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Mild (Mild)' reason for change: Data Entry Error		01 Feb 2021 21:32:52
User entered empty.		01 Feb 2021 21:30:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 21:32:52
User entered empty.		01 Feb 2021 21:30:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 21:32:52
User entered empty.		01 Feb 2021 21:30:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Moderate (Moderate)' reason for change: Data Entry Error		01 Feb 2021 21:32:52
User entered empty.		01 Feb 2021 21:30:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Moderate (Moderate)' reason for change: Data Entry Error		01 Feb 2021 21:32:52
User entered empty.		01 Feb 2021 21:30:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Moderate (Moderate)' reason for change: Data Entry Error		01 Feb 2021 21:32:52
User entered empty.		01 Feb 2021 21:30:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Mild (Mild)' reason for change: Data Entry Error		01 Feb 2021 21:32:52
User entered empty.		01 Feb 2021 21:30:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Severe (Severe)' reason for change: Data Entry Error		01 Feb 2021 21:32:52
User entered empty.		01 Feb 2021 21:30:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Severe (Severe)' reason for change: Data Entry Error		01 Feb 2021 21:32:52
User entered empty.		01 Feb 2021 21:30:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Mild (Mild)' reason for change: Data Entry Error		01 Feb 2021 21:32:52
User entered empty.		01 Feb 2021 21:30:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 21:32:52
User entered empty.		01 Feb 2021 21:30:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 21:32:52
User entered empty.		01 Feb 2021 21:30:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 21:32:52
User entered empty.		01 Feb 2021 21:30:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 21:32:52
User entered empty.		01 Feb 2021 21:30:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:43:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)' reason for change: Data Entry Error		01 Feb 2021 21:32:52
User entered empty.		01 Feb 2021 21:30:15

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Feb 2021 22:18:07
User entered 'Day 6 (Day 6)'		01 Feb 2021 21:34:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '07 Jan 2021'		01 Feb 2021 21:34:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '0'		01 Feb 2021 21:34:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '98'		01 Feb 2021 21:34:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User entered '%'	System	01 Feb 2021 21:34:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '97.5' F		01 Feb 2021 21:34:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:34:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:34:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:34:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:34:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Moderate (Moderate)'		01 Feb 2021 21:34:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:34:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:34:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Mild (Mild)'		01 Feb 2021 21:34:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Severe (Severe)'		01 Feb 2021 21:34:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Severe (Severe)'		01 Feb 2021 21:34:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:34:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:34:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:34:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:34:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:34:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:43:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:34:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:35:09

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '08 Jan 2021'		01 Feb 2021 21:35:09

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '0'		01 Feb 2021 21:35:09

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '93'		01 Feb 2021 21:35:09

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User entered '%'	System	01 Feb 2021 21:35:09

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '97.6' F		01 Feb 2021 21:35:09

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:35:09

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:35:09

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:35:09

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:35:09

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Mild (Mild)'		01 Feb 2021 21:35:09

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:35:09

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:35:09

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Mild (Mild)'		01 Feb 2021 21:35:09

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Severe (Severe)'		01 Feb 2021 21:35:09

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Severe (Severe)'		01 Feb 2021 21:35:09

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:35:09

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:35:09

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:35:09

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:35:09

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:35:09

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:43:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:35:09

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Day 9 (Day 9)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:36:22

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '09 Jan 2021'		01 Feb 2021 21:36:22

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '0'		01 Feb 2021 21:36:22

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '96'		01 Feb 2021 21:36:22

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User entered '%'	System	01 Feb 2021 21:36:22

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '97.1' F		01 Feb 2021 21:36:22

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:36:22

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:36:22

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:36:22

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:36:22

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Mild (Mild)'		01 Feb 2021 21:36:22

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:36:22

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:36:22

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Mild (Mild)'		01 Feb 2021 21:36:22

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Severe (Severe)'		01 Feb 2021 21:36:22

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Severe (Severe)'		01 Feb 2021 21:36:22

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:36:22

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:36:22

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:36:22

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:36:22

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:36:22

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:43:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:36:22

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Day 10 (Day 10)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 21:37:21

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '10 Jan 2021'		01 Feb 2021 21:37:21

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '0'		01 Feb 2021 21:37:21

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '100'		01 Feb 2021 21:37:21

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User entered '%'	System	01 Feb 2021 21:37:21

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '97.6' F		01 Feb 2021 21:37:21

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:37:21

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:37:21

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:37:21

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:37:21

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Mild (Mild)'		01 Feb 2021 21:37:21

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:37:21

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:37:21

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Mild (Mild)'		01 Feb 2021 21:37:21

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Severe (Severe)'		01 Feb 2021 21:37:21

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Severe (Severe)'		01 Feb 2021 21:37:21

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:37:21

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:37:21

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:37:21

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:37:21

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:37:21

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:43:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 21:37:21

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Day 11 (Day 11)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 22:08:11

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '11 Jan 2021'		01 Feb 2021 22:08:11

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '0'		01 Feb 2021 22:08:11

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '97'		01 Feb 2021 22:08:11

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User entered '%'	System	01 Feb 2021 22:08:11

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '97.7' F		01 Feb 2021 22:08:11

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:08:11

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:08:11

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:08:11

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:08:11

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Mild (Mild)'		01 Feb 2021 22:08:11

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:08:11

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:08:11

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:08:11

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Severe (Severe)'		01 Feb 2021 22:08:11

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Severe (Severe)'		01 Feb 2021 22:08:11

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:08:11

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:08:11

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:08:11

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:08:11

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:08:11

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:43:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:08:11

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Day 12 (Day 12)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 22:09:05

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '12 Jan 2021'		01 Feb 2021 22:09:05

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '0'		01 Feb 2021 22:09:05

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '98'		01 Feb 2021 22:09:05

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User entered '%'	System	01 Feb 2021 22:09:05

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '97.6' F		01 Feb 2021 22:09:05

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:09:05

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:09:05

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:09:05

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:09:05

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Mild (Mild)'		01 Feb 2021 22:09:05

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:09:05

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:09:05

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:09:05

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Moderate (Moderate)'		01 Feb 2021 22:09:05

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Moderate (Moderate)'		01 Feb 2021 22:09:05

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:09:05

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:09:05

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:09:05

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:09:05

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:09:05

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:43:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:09:05

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Day 13 (Day 13)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 22:09:45

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '13 Jan 2021'		01 Feb 2021 22:09:45

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '0'		01 Feb 2021 22:09:45

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '100'		01 Feb 2021 22:09:45

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User entered '%'	System	01 Feb 2021 22:09:45

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '97.5' F		01 Feb 2021 22:09:45

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:09:45

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:09:45

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:09:45

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:09:45

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Mild (Mild)'		01 Feb 2021 22:09:45

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:09:45

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:09:45

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:09:45

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Moderate (Moderate)'		01 Feb 2021 22:09:45

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Moderate (Moderate)'		01 Feb 2021 22:09:45

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:09:45

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:09:45

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:09:45

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:09:45

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:09:45

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:43:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:09:45

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Day 14 (Day 14)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 22:10:24

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '14 Jan 2021'		01 Feb 2021 22:10:24

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '0'		01 Feb 2021 22:10:24

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '98'		01 Feb 2021 22:10:24

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User entered '%'	System	01 Feb 2021 22:10:24

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '97.0' F		01 Feb 2021 22:10:24

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:10:24

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:10:24

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:10:24

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:10:24

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:10:24

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:10:24

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:10:24

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:10:24

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Moderate (Moderate)'		01 Feb 2021 22:10:24

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Moderate (Moderate)'		01 Feb 2021 22:10:24

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:10:24

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:10:24

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:10:24

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:10:24

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:10:24

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:43:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:10:24

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Day 15 (Day 15)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 22:16:26

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '15 Jan 2021'		01 Feb 2021 22:16:26

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '0'		01 Feb 2021 22:16:26

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '98'		01 Feb 2021 22:16:26

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User entered '%'	System	01 Feb 2021 22:16:26

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '95.9' F		01 Feb 2021 22:16:26

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:16:26

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:16:26

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:16:26

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:16:26

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:16:26

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:16:26

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:16:26

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:16:26

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Mild (Mild)'		01 Feb 2021 22:16:26

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Mild (Mild)'		01 Feb 2021 22:16:26

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:16:26

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:16:26

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:16:26

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:16:26

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:16:26

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:43:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:16:26

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Day 16 (Day 16)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 22:17:16

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '16 Jan 2021'		01 Feb 2021 22:17:16

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '0'		01 Feb 2021 22:17:16

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '99'		01 Feb 2021 22:17:16

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User entered '%'	System	01 Feb 2021 22:17:16

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '97.7' F		01 Feb 2021 22:17:16

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:16

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:16

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:16

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:16

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:16

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:16

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:16

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:16

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Mild (Mild)'		01 Feb 2021 22:17:16

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'Mild (Mild)'		01 Feb 2021 22:17:16

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:16

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:16

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:16

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:16

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:16

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:43:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:16

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Day 17 (Day 17)'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 22:17:47

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '17 Jan 2021'		01 Feb 2021 22:17:47

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '0'		01 Feb 2021 22:17:47

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '98'		01 Feb 2021 22:17:47

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User entered '%'	System	01 Feb 2021 22:17:47

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered '97.7' F		01 Feb 2021 22:17:47

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:47

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:47

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:47

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:47

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:47

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:47

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:47

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:47

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:47

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:47

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:47

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:47

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:47

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:47

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:47

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:43:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:38
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:44:25
User entered 'None (None)'		01 Feb 2021 22:17:47

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:38

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:07:29
User entered '04 Jan 2021'		07 Jan 2021 20:38:52

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:38

[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 21:57:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:07:29
User entered 'Yes (Y)'		07 Jan 2021 20:38:52

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:38

[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 21:57:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:29
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).		12 Jan 2021 09:49:22
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'Confirmed, AE log was updated' (Site from System).		07 Jan 2021 21:13:25
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	07 Jan 2021 20:38:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Jan 2021 20:38:52

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:38

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:07:29
User entered '04 Jan 2021'		07 Jan 2021 20:38:52

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:38

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:29
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'		07 Jan 2021 20:38:52

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:38

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:07:29
User entered empty.		07 Jan 2021 20:38:52

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:38

[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 21:57:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:29
User entered 'No (N)'		07 Jan 2021 20:38:52

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:38

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:29
User entered empty.		07 Jan 2021 20:38:52

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:38

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:31
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:29
User entered empty.		07 Jan 2021 20:38:52

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:43:38

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:31
User entered '1'	System	07 Jan 2021 20:38:52

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

Did the subject have Respiratory Rates  $\geq$  30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:07:52
User entered 'No (N)'		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:52
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 21:12:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Jan 2021 21:12:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 21:12:17
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 21:12:03
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:46:48
User closed query 'Please verify as symptom log shows an O2 of 93% on 08Jan2021. Please update this and the next three fields to match data on symptom log.' (Site from CRA).		09 Feb 2021 19:45:25
Query 'Please verify as symptom log shows an O2 of 93% on 08Jan2021. Please update this and the next three fields to match data on symptom log.' answered with 'Corrected' (Site from CRA).		09 Feb 2021 00:47:24
DataPoint Un-verified.		09 Feb 2021 00:47:12
User entered 'Yes (Y)' reason for change: Data Entry Error		09 Feb 2021 00:47:12
User opened query 'Please verify as symptom log shows an O2 of 93% on 08Jan2021. Please update this and the next three fields to match data on symptom log.' (Site from CRA).		02 Feb 2021 21:32:26
DataPoint Verified.		28 Jan 2021 20:07:52
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 21:12:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Jan 2021 21:12:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 21:12:26
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 21:12:03
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
DataPoint Verified.		01 Apr 2021 22:31:31
User closed query 'As symptom log shows an O2 of 93% on 08Jan2021, please update this field. ' (Site from CRA).		01 Apr 2021 22:31:14
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Query 'As symptom log shows an O2 of 93% on 08Jan2021, please update this field. ' answered with 'Updated Missing Data ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 18:31:41
DataPoint Un-verified.		15 Feb 2021 18:31:31
User entered '08 Jan 2021' reason for change: Data Entry Error		15 Feb 2021 18:31:31
User opened query 'As symptom log shows an O2 of 93% on 08Jan2021, please update this field. ' (Site from CRA).		09 Feb 2021 19:46:18
DataPoint Verified.		28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
DataPoint Verified.		01 Apr 2021 22:31:42
User closed query 'As symptom log shows an O2 of 93% on 08Jan2021, please update this field. ' (Site from CRA).		01 Apr 2021 22:30:33
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Query 'As symptom log shows an O2 of 93% on 08Jan2021, please update this field. ' answered with 'Updated Missing Data ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 18:31:45
DataPoint Un-verified.		15 Feb 2021 18:31:31
User entered '08 Jan 2021' reason for change: Data Entry Error		15 Feb 2021 18:31:31
User opened query 'As symptom log shows an O2 of 93% on 08Jan2021, please update this field. ' (Site from CRA).		09 Feb 2021 19:46:27
DataPoint Verified.		28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
DataPoint Verified.		01 Apr 2021 22:31:52
User closed query 'As symptom log shows an O2 of 93% on 08Jan2021, please update this field. ' (Site from CRA).		01 Apr 2021 22:30:53
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Query 'As symptom log shows an O2 of 93% on 08Jan2021, please update this field. ' answered with 'Updated Missing Data ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 18:31:50
DataPoint Un-verified.		15 Feb 2021 18:31:31
User entered '93' reason for change: Data Entry Error		15 Feb 2021 18:31:31
User opened query 'As symptom log shows an O2 of 93% on 08Jan2021, please update this field. ' (Site from CRA).		09 Feb 2021 19:46:35
DataPoint Verified.		28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:52
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 21:12:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Jan 2021 21:12:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 21:12:43
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 21:12:03
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:52
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 21:12:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Jan 2021 21:12:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 21:12:17
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 21:12:03
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:52
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 21:12:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Jan 2021 21:12:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 21:12:17
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 21:12:03
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:52
User entered 'No (N)'		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Evidence of Shock Requires Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:52
User entered 'No (N)'		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:52
User entered 'No (N)'		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Covid-19 Assessment 01 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:43:38

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:27
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:07:52
User entered empty.		07 Jan 2021 21:12:03

US3462374

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:43:38

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User accepted default value 'Day 3 (Day 3)'		07 Jan 2021 20:27:56

US3462374

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:43:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:21
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:15:11
User entered 'Yes (Y)'		07 Jan 2021 20:27:56

US3462374

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:43:38

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:21
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:15:13
User entered '06 Jan 2021'		07 Jan 2021 20:27:56

US3462374

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:43:38

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User accepted default value 'Day 5 (Day 5)'		07 Jan 2021 20:27:56

US3462374

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:43:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:15:18
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Jan 2021 17:56:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Jan 2021 17:56:50
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 17:56:50
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 20:27:56
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 20:27:56

US3462374

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:43:38

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:21
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08JAN2021 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. (Site from DM). Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08JAN2021 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Confirmed, samples have been received by PPD' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08JAN2021 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 10:39:24 09 Feb 2021 00:49:40 29 Jan 2021 06:06:52
User entered '08 Jan 2021' reason for change: Data Entry Error		28 Jan 2021 20:15:20 11 Jan 2021 17:56:50
User entered empty.		07 Jan 2021 20:27:56

US3462374

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:43:38

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User accepted default value 'Day 7 (Day 7)'		07 Jan 2021 20:27:56

US3462374

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:43:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:48:24
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 00:49:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 00:49:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 00:49:16
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 20:27:56
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 20:27:56

US3462374

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:43:38

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:48:24
User entered '10 Jan 2021' reason for change: Data Entry Error		09 Feb 2021 00:49:16
User entered empty.		07 Jan 2021 20:27:56

US3462374

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:43:38

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User accepted default value 'Day 9 (Day 9)'		07 Jan 2021 20:27:56

US3462374

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:43:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:48:24
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 00:49:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 00:49:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 00:49:16
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 20:27:56
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 20:27:56

US3462374

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:43:38

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:48:24
User entered '12 Jan 2021' reason for change: Data Entry Error		09 Feb 2021 00:49:16
User entered empty.		07 Jan 2021 20:27:56

US3462374

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:43:38

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User accepted default value 'Day 14 (Day 14)'		07 Jan 2021 20:27:56

US3462374

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:43:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:48:24
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 00:49:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 00:49:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 00:49:16
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 20:27:56
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 20:27:56

US3462374

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:43:38

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:48:24
User entered '17 Jan 2021' reason for change: Data Entry Error		09 Feb 2021 00:49:16
User entered empty.		07 Jan 2021 20:27:56

US3462374

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:43:38

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User accepted default value 'Day 21 (Day 21)'		07 Jan 2021 20:27:56

US3462374

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:43:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:48:24
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 00:49:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 00:49:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 00:49:16
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 20:27:56
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 20:27:56

US3462374

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:43:38

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:48:24
User entered '24 Jan 2021' reason for change: Data Entry Error		09 Feb 2021 00:49:16
User entered empty.		07 Jan 2021 20:27:56

US3462374

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:43:38

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User accepted default value 'Day 28 (Day 28)'		07 Jan 2021 20:27:56

US3462374

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:43:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	30 Mar 2021 00:58:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:48:24
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 00:49:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 00:49:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 00:49:16
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 20:27:56
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 20:27:56

US3462374

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:43:38

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01FEB2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).		19 Apr 2021 06:44:58
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01FEB2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Sample shipped to Viracor on 02Feb21. UPS tracking number 9148 9786 0573. ' (Site from DM).		06 Apr 2021 17:32:00
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01FEB2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).		06 Apr 2021 08:34:42
DataPoint Verified.		01 Apr 2021 22:36:52
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04FEB2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).		31 Mar 2021 04:10:26
User signature succeeded.	Gregg Lucksinger (b) (4) (b) (4)	30 Mar 2021 00:58:21

US3462374

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:43:38

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04FEB2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Corrected date of collection' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	29 Mar 2021 19:23:52
		29 Mar 2021 19:22:39
User entered '01 Feb 2021' reason for change: Data Entry Error		29 Mar 2021 19:22:39
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04FEB2021 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM). DataPoint Verified.		18 Feb 2021 04:35:48
		09 Feb 2021 19:48:24
User entered '04 Feb 2021' reason for change: Data Entry Error		09 Feb 2021 00:49:16
User entered empty.		07 Jan 2021 20:27:56

US3462374

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:08:42
User entered 'Yes (Y)'		07 Jan 2021 20:24:21

US3462374

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:08:42
User entered '04 Jan 2021'		07 Jan 2021 20:24:21

US3462374

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[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 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:08:42
User entered 'Clinic (Clinic)'		07 Jan 2021 20:24:21

US3462374

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User entered 'SICKD1'	System	07 Jan 2021 20:24:21

US3462374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:10:39
User entered 'Yes (Y)'		07 Jan 2021 20:25:53

US3462374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:10:39
User entered '04 Jan 2021'		07 Jan 2021 20:25:53

US3462374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:10:39
User entered '10:12'		07 Jan 2021 20:25:53

US3462374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User entered '04 Jan 2021 10:12'	System	07 Jan 2021 20:25:53

US3462374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:10:39
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Jan 2021 20:27:11
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	07 Jan 2021 20:27:11
User entered '191' cm reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 20:27:11
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Jan 2021 20:25:53
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 20:25:53
DataPoint set to visible.	System	07 Jan 2021 20:24:21

US3462374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:10:39
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Jan 2021 20:27:11
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	07 Jan 2021 20:27:11
User entered '81' kg reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 20:27:11
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Jan 2021 20:25:53
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 20:25:53
DataPoint set to visible.	System	07 Jan 2021 20:24:21

US3462374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:10:39
User entered '97.3' F		07 Jan 2021 20:25:53

US3462374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:47:24
User closed query 'Per source page, 'Oral' temperature was completed. Please clarify. ' (Site from CRA).		09 Feb 2021 19:47:19
Query 'Per source page, 'Oral' temperature was completed. Please clarify. ' answered with 'Corrected' (Site from CRA).		02 Feb 2021 20:05:20
User closed query 'Route of measurement is not Other, however, specify is provided. Please correct.' (Site from System).	System	02 Feb 2021 20:05:13
User opened query 'Route of measurement is not Other, however, specify is provided. Please correct.' (Site from System).	System	02 Feb 2021 20:05:07
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 20:05:07
User entered 'Oral (Oral)' reason for change: Data Entry Error		02 Feb 2021 20:05:07
DataPoint Verified.		28 Jan 2021 20:10:39
User opened query 'Per source page, 'Oral' temperature was completed. Please clarify. ' (Site from CRA).		28 Jan 2021 20:10:05
User entered 'Other (Other)'		07 Jan 2021 20:25:53

US3462374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:47:24
DataPoint Un-verified.		02 Feb 2021 20:05:13
User entered empty; reason for change Data Entry Error		02 Feb 2021 20:05:13
DataPoint Verified.		28 Jan 2021 20:10:39
User entered 'Forehead'		07 Jan 2021 20:25:53

US3462374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:10:39
User entered '57'		07 Jan 2021 20:25:53

US3462374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User entered 'bpm'	System	07 Jan 2021 20:25:53

US3462374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:10:39
User entered '16'		07 Jan 2021 20:25:53

US3462374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User entered 'breaths/min'	System	07 Jan 2021 20:25:53

US3462374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:10:39
User entered '109'		07 Jan 2021 20:25:53

US3462374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User entered 'mmHg'	System	07 Jan 2021 20:25:53

US3462374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:10:39
User entered '73'		07 Jan 2021 20:25:53

US3462374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User entered 'mmHg'	System	07 Jan 2021 20:25:53

US3462374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08

US3462374

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08

US3462374

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:10:48
User entered 'Yes (Y)'		07 Jan 2021 20:27:26

US3462374

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:10:48
User entered '04 Jan 2021'		07 Jan 2021 20:27:26

US3462374

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:43:38

[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 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 20:10:54
User entered 'Yes (Y)'		07 Jan 2021 20:27:38

US3462374

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:43:38

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:44:08
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:10:54
User entered '04 Jan 2021'		07 Jan 2021 20:27:38

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:51
User closed query 'Per GCL Lab Reconciliation: Swab: DM has a 01FEB2021 Sailva sample with Accession # 1F619142189 and Requisition kit ID 1F617670767 labelled in Viracor as Subject ID US3462374- Illness Day 28 and in GCL as Subject US3462375- Unscheduled visit . Please confirm in the response the correct subject ID, correct visit and correct date for the requisition kit ID and record the data in EDC.' (Site from DM).		28 Apr 2021 08:54:35
Query 'Per GCL Lab Reconciliation: Swab: DM has 01FEB2021 Sailva sample with Accession # 1F619142189 and Requisition kit ID 1F617670767 labelled in Viracor as Subject ID US3462374- Illness Day 28 and in GCL as Subject US3462375- Unscheduled visit . Please confirm in the response the correct subject ID, correct visit and correct date for the requisition kit ID and record the data in EDC.' answered with ' Sailva sample with Accession # 1F619142189 and Requisition kit ID 1F617670767 correspond to patient# US3462374, Day 28 Illness/Convalescence visit, date: 01FEB2021.' (Site from DM).		29 Mar 2021 19:25:05
User opened query 'Per GCL Lab Reconciliation: Swab: DM has a 01FEB2021 Sailva sample with Accession # 1F619142189 and Requisition kit ID 1F617670767 labelled in Viracor as Subject ID US3462374- Illness Day 28 and in GCL as Subject US3462375- Unscheduled visit . Please confirm in the response the correct subject ID, correct visit and correct date for the requisition kit ID and record the data in EDC.' (Site from DM).		09 Mar 2021 07:22:47
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:47:42
User entered 'Yes (Y)'		02 Feb 2021 19:59:57

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:51
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:47:42
User entered '01 Feb 2021'		02 Feb 2021 19:59:57

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:51
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:47:42
User entered 'Clinic (Clinic)'		02 Feb 2021 19:59:57

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:51
User entered 'SICKD28'	System	02 Feb 2021 19:59:57

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:47:48
User entered 'Yes (Y)'		02 Feb 2021 20:02:47

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:47:48
User entered '01 Feb 2021'		02 Feb 2021 20:02:47

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:47:48
User entered '15:00'		02 Feb 2021 20:02:47

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:48
User entered '01 Feb 2021 15:00'	System	02 Feb 2021 20:02:47

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:47:48
User entered '191' cm		02 Feb 2021 20:02:47
DataPoint set to visible.	System	02 Feb 2021 19:59:57

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:47:48
User entered '82' kg		02 Feb 2021 20:02:47
DataPoint set to visible.	System	02 Feb 2021 19:59:57

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:47:48
User entered '97.8' F		02 Feb 2021 20:02:47

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:47:48
User entered 'Oral (Oral)'		02 Feb 2021 20:02:47

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:47:48
User entered empty.		02 Feb 2021 20:02:47

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:47:48
User entered '62'		02 Feb 2021 20:02:47

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:48
User entered 'bpm'	System	02 Feb 2021 20:02:47

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:47:48
User entered '16'		02 Feb 2021 20:02:47

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:48
User entered 'breaths/min'	System	02 Feb 2021 20:02:47

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:47:48
User entered '115'		02 Feb 2021 20:02:47

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:48
User entered 'mmHg'	System	02 Feb 2021 20:02:47

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:48
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:47:48
User entered '71'		02 Feb 2021 20:02:47

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:48
User entered 'mmHg'	System	02 Feb 2021 20:02:47

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:48

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:43:38

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:48

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:45
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:47:56
User entered 'Yes (Y)'		02 Feb 2021 20:03:11

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:45
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:47:56
User entered '01 Feb 2021'		02 Feb 2021 20:03:11

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:43:38

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:48:02
User entered 'Yes (Y)'		02 Feb 2021 20:03:34

US3462374

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:43:38

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:42
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:48:02
User entered '01 Feb 2021'		02 Feb 2021 20:03:34

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered 'Yes (Y)'	(b) (4) (o) (4), (b) (6)	12 Mar 2021 16:54:16

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:54:16

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[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 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:54:16

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User entered 'UNBLND_DECIDE'	System	12 Mar 2021 16:54:16

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:43:38

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:54:52

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:43:38

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '0'	(b) (4) (p) (4), (b) (6)	12 Mar 2021 16:54:52

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:43:38

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:54:52

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:43:38

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:54:52

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:43:38

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:54:52

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:43:38

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:54:52

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:43:38

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:54:52

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:43:38

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered 'Placebo (Placebo)'	(b) (4) (p) (4), (b) (6)	12 Mar 2021 16:54:52

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:43:38

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:54:52

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:43:38

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User entered '1'	System	12 Mar 2021 16:54:52

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:43:38

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User entered '1'	System	12 Mar 2021 16:54:52

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '191' cm	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:57:04

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '81' kg	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:57:04

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User entered '22.20334'	System	12 Mar 2021 16:57:04
DataPoint set to visible.	System	12 Mar 2021 16:54:52

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:38

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '191' cm	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:57:04

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '81' kg	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:57:04

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User entered '22.20334'	System	12 Mar 2021 16:57:04
DataPoint set to visible.	System	12 Mar 2021 16:54:52

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User accepted default value 'Pre-Dose (PREDOSE)'		12 Mar 2021 16:57:04

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered 'Yes (Y)'	(b) (4) (o) (4), (b) (6)	12 Mar 2021 16:57:04

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:57:04

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '15:46'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:57:04

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User entered '11 Mar 2021 15:46'	System	12 Mar 2021 16:57:04

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:57:04

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 20:28:31
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:25:09
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	05 Apr 2021 20:25:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:57:04

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 20:28:31
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:25:09
User entered 'Tympanic' reason for change: Data Entry Error		05 Apr 2021 20:25:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:57:04

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '62'	(b) (4) (p) (4), (b) (6)	12 Mar 2021 16:57:04

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User entered 'bpm'	System	12 Mar 2021 16:57:04

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '16'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:57:04

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User entered 'breaths/min'	System	12 Mar 2021 16:57:04

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '103'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:57:04

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User entered 'mmHg'	System	12 Mar 2021 16:57:04

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '70'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:57:04

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User entered 'mmHg'	System	12 Mar 2021 16:57:04

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '191' cm	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:57:04

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '81' kg	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:57:04

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:43:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User entered '22.20334'	System	12 Mar 2021 16:57:04
DataPoint set to visible.	System	12 Mar 2021 16:54:52

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User accepted default value 'Post-Dose (POSTDOSE)'		12 Mar 2021 16:57:49

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:57:49

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:57:49

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '16:00'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:57:49

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User entered '11 Mar 2021 16:00'	System	12 Mar 2021 16:57:49

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:57:49

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 20:28:31
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:25:09
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	05 Apr 2021 20:25:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:57:49

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	05 Apr 2021 20:28:31
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:25:09
User entered 'Tympanic' reason for change: Data Entry Error		05 Apr 2021 20:25:09
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:57:49

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '62'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:57:49

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User entered 'bpm'	System	12 Mar 2021 16:57:49

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '16'	(b) (4) (p) (4), (b) (6)	12 Mar 2021 16:57:49

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User entered 'breaths/min'	System	12 Mar 2021 16:57:49

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '117'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:57:49

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User entered 'mmHg'	System	12 Mar 2021 16:57:49

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '70'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:57:49

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User entered 'mmHg'	System	12 Mar 2021 16:57:49

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:58:03

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:58:03

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:58:23

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:58:23

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:58:23

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User entered 'mRNA-1273'	System	12 Mar 2021 16:58:23
DataPoint set to visible.	System	12 Mar 2021 16:54:52

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:58:23

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '16:00'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:58:23

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User entered '11 Mar 2021 16:00'	System	12 Mar 2021 16:58:23

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:58:23

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User entered 'ONCE'	System	12 Mar 2021 16:58:23

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User entered 'INTRAMUSCULAR'	System	12 Mar 2021 16:58:23

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:55:04

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:55:04

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '15:27'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:55:04

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:43:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User entered '11 Mar 2021 15:27'	System	12 Mar 2021 16:55:04

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:43:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:55:14

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:43:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:55:14

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:43:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered '15:21'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:55:14

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:43:38

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User entered '11 Mar 2021 15:21'	System	12 Mar 2021 16:55:14

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:55:19

US3462374

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:30:00
User entered '1'	System	12 Mar 2021 16:55:19

US3462374

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:26:11
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:39:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:16:52

US3462374

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:26:11
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:39:22
User entered '18 Mar 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:16:52

US3462374

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:26:11
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:39:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:16:52

US3462374

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:43:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:26:11
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:39:22
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:16:52

US3462374

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:26:11
User signature succeeded.	Gregg Lucksinger (b) (4)	31 Mar 2021 21:39:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:16:59

US3462374

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:26:11
User entered '1'	System	31 Mar 2021 19:16:59

US3462374

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:26:11
User entered '1'	System	31 Mar 2021 19:16:59
DataPoint set to visible.	System	31 Mar 2021 19:16:59

US3462374

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:01:15

US3462374

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered '08 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:01:15

US3462374

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:01:15

US3462374

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:43:38

[Folder OID](#)

---

Audit	User	Time (GMT)
User entered 'OLD29'	System	09 Apr 2021 16:01:15

---

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	09 Apr 2021 16:02:27

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:02:27

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered '08 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:02:27

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered '15:35'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:02:27

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Vital Signs Date and Time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '08 Apr 2021 15:35'	System	09 Apr 2021 16:02:27

---

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:02:27

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered 'Oral (Oral)'	(b) (4) (d) (4), (b) (6)	09 Apr 2021 16:02:27

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered empty.	(b) (4) (d) (4), (b) (6)	09 Apr 2021 16:02:27

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered '57'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:02:27

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Pulse units](#)

---

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Apr 2021 16:02:27

---

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered '13'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:02:27

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Respiratory Rate units](#)

---

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Apr 2021 16:02:27

---

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered '91'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:02:27

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Systolic Blood Pressure units](#)

---

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 16:02:27

---

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). User signature succeeded.	(b) (4), (b) (6)	13 Apr 2021 12:28:14
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' ' (Site from System).	Gregg Lucksinger (b) (4) (b) (4) (b) (4), (b) (6)	09 Apr 2021 20:36:45 09 Apr 2021 16:02:45
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		09 Apr 2021 16:02:27
User entered '58'	(b) (4), (b) (6)	09 Apr 2021 16:02:27

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:43:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 16:02:27

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	09 Apr 2021 16:09:25

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:09:25

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered '08 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:09:25

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered '16:42'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:09:25

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Apr 2021 16:42'	System	09 Apr 2021 16:09:25

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:09:25

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered 'Oral (Oral)'	(b) (4) (d) (4), (b) (6)	09 Apr 2021 16:09:25

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered empty.	(b) (4) (d) (4), (b) (6)	09 Apr 2021 16:09:25

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered '60'	(b) (4) (d) (4), (b) (6)	09 Apr 2021 16:09:25

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Pulse units](#)

---

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Apr 2021 16:09:25

---

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered '13'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:09:25

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Respiratory Rate units](#)

---

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Apr 2021 16:09:25

---

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered '112'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:09:25

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 16:09:25

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered '76'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:09:25

US3462374

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:43:38

[Diastolic Blood Pressure units](#)

---

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 16:09:25

---

US3462374

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered 'No (N)'	(b) (4) (d) (4), (b) (6)	09 Apr 2021 16:09:54

US3462374

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:43:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:09:54

US3462374

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:10:20

US3462374

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered empty.	(b) (4) (d) (4), (b) (6)	09 Apr 2021 16:10:20

US3462374

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:10:20

US3462374

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	09 Apr 2021 16:10:20
DataPoint set to visible.	System	31 Mar 2021 19:16:59

US3462374

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered '08 Apr 2021'	(b) (4) (d) (4), (b) (6)	09 Apr 2021 16:10:20

US3462374

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered '16:11'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:10:20

US3462374

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[Treatment Date and Time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '08 Apr 2021 16:11'	System	09 Apr 2021 16:10:20

---

US3462374

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System). User signature succeeded.	(b) (4), (b) (6)	16 Apr 2021 14:00:31
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered with 'Per Subjects Request, okay Per PI ' (Site from System). User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System). User entered 'Right Arm (RIGHT ARM)'	Gregg Lucksinger (b) (4) (b) (4) (b) (4), (b) (6) System	09 Apr 2021 20:36:45 09 Apr 2021 16:10:44 09 Apr 2021 16:10:20 09 Apr 2021 16:10:20

US3462374

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[What was the frequency of the study treatment dosing?](#)

---

Audit	User	Time (GMT)
User entered 'ONCE'	System	09 Apr 2021 16:10:20

---

US3462374

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:43:38

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	09 Apr 2021 16:10:20

US3462374

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	09 Apr 2021 20:36:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:11:01

US3462374

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:43:38

[Continuing Flag](#)

---

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 16:11:01

---

US3462374

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:43:38

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:19:50
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:48:32
User entered 'Yes (Y)'		07 Jan 2021 20:28:14

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:35:55
Reviewed for Safety.		08 Jan 2021 17:34:48
User entered 'USA-US093-2021-mRNA-1273-P301000002'	System	08 Jan 2021 17:34:43
User entered 'New'	(b) (4), (b) (6)	08 Jan 2021 17:34:43

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:50:21
User closed query 'Per eCRF Guidelines, please use the term "Symptomatic COVID-19" or "COVID-19" (Site from CRA).		09 Feb 2021 19:48:43
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Feb 2021 20:08:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Feb 2021 20:08:35
Data point term sent to Coder	System	02 Feb 2021 20:07:21
Query 'Per eCRF Guidelines, please use the term "Symptomatic COVID-19" or "COVID-19" answered with 'Corrected' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 20:07:12
DataPoint Un-verified.		02 Feb 2021 20:07:03
Coding entries removed.		02 Feb 2021 20:07:03
User entered 'COVID-19' reason for change: Data Entry Error		02 Feb 2021 20:07:03
DataPoint Verified.		28 Jan 2021 19:35:55
User opened query 'Per eCRF Guidelines, please use the term "Symptomatic COVID-19" or "COVID-19" (Site from CRA).		28 Jan 2021 19:32:17
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Jan 2021 20:41:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Jan 2021 20:41:44
Data point term sent to Coder	System	07 Jan 2021 20:41:05
User entered 'Covid-19 Infection'	(b) (4), (b) (6)	07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:50:23
User closed query 'Per eCRF Guidelines, any confirmed SARS-CoV-2 infection or COVID-19 should be recorded as an MAAE. Please clarify. ' (Site from CRA).		09 Feb 2021 19:48:48
Query 'Per eCRF Guidelines, any confirmed SARS-CoV-2 infection or COVID-19 should be recorded as an MAAE. Please clarify. ' answered with 'Corrected' (Site from CRA).		09 Feb 2021 00:47:49
DataPoint Un-verified.		09 Feb 2021 00:47:45
User entered 'Yes (Y)' reason for change: Data Entry Error		09 Feb 2021 00:47:45
DataPoint Verified.		28 Jan 2021 19:35:55
User opened query 'Per eCRF Guidelines, any confirmed SARS-CoV-2 infection or COVID-19 should be recorded as an MAAE. Please clarify. ' (Site from CRA).		28 Jan 2021 19:33:54
User entered 'No (N)'		07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (v) (4), (b) (6)	28 Jan 2021 19:35:55
User entered 'No (N)'		07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:35:55
User entered 'Yes (Y)'		07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 19:35:55
User entered '01 Jan 2021'		07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:35:55
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	07 Jan 2021 20:40:35
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 20:40:35
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	07 Jan 2021 20:40:13
User entered '20:00'	(b) (4), (b) (6)	07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Jan 2021 20:40:35
User entered '01 Jan 2021 20:00'	System	07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	09 Feb 2021 19:49:31
DataPoint Un-verified.		02 Feb 2021 20:07:03
User entered 'No (N)' reason for change: Data Entry Error		02 Feb 2021 20:07:03
DataPoint Verified.		28 Jan 2021 19:35:55
User entered 'Yes (Y)'		07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:08:29
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Corrected' (Site from Safety). DataPoint Un-verified.		09 Feb 2021 19:49:33
User entered '17 Jan 2021' reason for change: Data Entry Error		02 Feb 2021 20:07:43
DataPoint Verified.		02 Feb 2021 20:07:03
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty.		02 Feb 2021 20:07:03
		28 Jan 2021 19:35:55
		15 Jan 2021 18:58:10
		07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:35:55
User entered empty.		07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

[AE End Date and Time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	07 Jan 2021 20:40:13

---

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	09 Feb 2021 19:49:10
User closed query 'Per source AE Log, event listed with Severity of Grade 2/Mod. Please clarify. ' (Site from CRA).		09 Feb 2021 19:49:08
Query 'Per source AE Log, event listed with Severity of Grade 2/Mod. Please clarify. ' answered with 'Corrected' (Site from CRA).		02 Feb 2021 20:07:47
DataPoint Un-verified.		02 Feb 2021 20:07:03
User entered 'Grade 2/Moderate (Grade 2/Moderate) reason for change: Data Entry Error		02 Feb 2021 20:07:03
DataPoint Verified.		28 Jan 2021 19:35:55
User opened query 'Per source AE Log, event listed with Severity of Grade 2/Mod. Please clarify. ' (Site from CRA).		28 Jan 2021 19:35:00
User entered 'Grade 1/Mild (Grade 1/Mild)'		07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:35:55
User entered 'No (N)'		07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	28 Jan 2021 19:35:55
User entered '0'		07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	28 Jan 2021 19:35:55
User entered '0'		07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	28 Jan 2021 19:35:55
User entered '0'		07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:35:55
User entered empty.		07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:35:55
User entered empty.		07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:35:55
User entered empty.		07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	28 Jan 2021 19:35:55
User entered empty.		07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:35:55
User entered '0'		07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	28 Jan 2021 19:35:55
User entered '0'		07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (o) (4), (b) (6)	28 Jan 2021 19:35:55
User entered '0'		07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 19:35:55
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 20:40:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Jan 2021 20:40:35
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 20:40:35
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 20:40:13
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 19:35:55
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 20:40:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Jan 2021 20:40:35
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 20:40:35
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 20:40:13
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User closed query 'PV Query: As the last dose of study drug was given on 24 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:08:34
Query 'PV Query: As the last dose of study drug was given on 24 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'Corrected' (Site from Safety). DataPoint Un-verified.		09 Feb 2021 19:49:47
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error DataPoint Verified.		02 Feb 2021 20:07:53
User opened query 'PV Query: As the last dose of study drug was given on 24 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).		02 Feb 2021 20:07:03
User closed query 'Data is required. Please complete.' (Site from System). Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Feb 2021 20:07:03
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Jan 2021 19:35:55
User opened query 'Data is required. Please complete.' (Site from System). User entered empty.	System	15 Jan 2021 18:57:36
	(b) (4), (b) (6)	07 Jan 2021 20:40:35
		07 Jan 2021 20:40:35
	(b) (4), (b) (6)	07 Jan 2021 20:40:35
		07 Jan 2021 20:40:13
	(b) (4), (b) (6)	07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

None

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User closed query 'Per source Illness Visit 1, the subject was noted as taking (Ibuprofen 01/01/21). Please clarify entry and determine if ConMeds pages in source and eCRF should be updated. ' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:49:58
Query 'Per source Illness Visit 1, the subject was noted as taking (Ibuprofen 01/01/21). Please clarify entry and determine if ConMeds pages in source and eCRF should be updated. ' answered with 'Corrected' (Site from CRA). DataPoint Un-verified.		09 Feb 2021 19:49:55
		02 Feb 2021 20:07:56
		02 Feb 2021 20:07:03
User entered '0' reason for change: Data Entry Error		02 Feb 2021 20:07:03
User opened query 'Per source Illness Visit 1, the subject was noted as taking (Ibuprofen 01/01/21). Please clarify entry and determine if ConMeds pages in source and eCRF should be updated. ' (Site from CRA). DataPoint Verified.		28 Jan 2021 20:07:04
		28 Jan 2021 19:35:55
User entered '1'		07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4) (d) (4), (b) (6)	10 Feb 2021 18:08:38
DataPoint Verified.		09 Feb 2021 19:50:04
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Updated in Con Med CRF' (Site from Safety).		02 Feb 2021 20:08:13
DataPoint Un-verified.		02 Feb 2021 20:07:03
User entered '1' reason for change: Data Entry Error		02 Feb 2021 20:07:03
DataPoint Verified.		28 Jan 2021 19:35:55
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		15 Jan 2021 19:03:58
User entered '0'		07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (o) (4), (b) (6)	28 Jan 2021 19:35:55
User entered '0'		07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). DataPoint Verified.	(b) (4) (D) (4), (b) (6)	10 Feb 2021 18:08:40
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Corrected' (Site from Safety). DataPoint Un-verified.		09 Feb 2021 19:50:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error DataPoint Verified.		02 Feb 2021 20:08:17
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'		02 Feb 2021 20:07:03
		02 Feb 2021 20:07:03
		28 Jan 2021 19:35:55
		15 Jan 2021 18:58:26
		07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	28 Jan 2021 19:35:55
User entered empty.		07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User closed query 'PV Query: Please complete the Covid-19 Assessments tab, including symptoms log and severity assessment.' (Site from Safety).	(b) (4), (b) (6)	10 Feb 2021 18:08:43
Query 'PV Query: Please complete the Covid-19 Assessments tab, including symptoms log and severity assessment.' answered with 'Corrected' (Site from Safety).		02 Feb 2021 20:08:21
DataPoint Verified.		28 Jan 2021 19:35:55
Query 'PV Query: Did the patient have any known exposure to Covid-19?' canceled (Site from Safety).		15 Jan 2021 19:05:55
User opened query 'PV Query: Did the patient have any known exposure to Covid-19?' (Site from Safety).		15 Jan 2021 18:58:36
User opened query 'PV Query: Please complete the Covid-19 Assessments tab, including symptoms log and severity assessment.' (Site from Safety).		15 Jan 2021 18:57:47
User entered empty.		07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	07 Jan 2021 20:40:13

US3462374

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:43:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	09 Feb 2021 00:47:45
User entered '0'	System	07 Jan 2021 20:40:13

---

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:43:38

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:19:50
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Danuel Hamlin (b) (4)	31 Oct 2020 17:50:21
User entered 'No (N)'	(b) (4), (b) (6)	30 Aug 2020 20:24:03

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	31 Oct 2020 17:52:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Oct 2020 17:52:27
Data point term sent to Coder	System	31 Oct 2020 17:51:43
User entered 'Lexapro'	Danuel Hamlin (b) (4) (b) (4)	31 Oct 2020 17:50:54

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	31 Oct 2020 17:50:54
	(b) (4)	
	(b) (4)	

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Mild Depression'	(b) (4) Danuel Hamlin (b) (4)	31 Oct 2020 17:50:54
	(b) (4)	
	(b) (4)	

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered '10'	(b) (4) Danuel Hamlin (b) (4)	31 Oct 2020 17:50:54
	(b) (4)	
	(b) (4)	

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'mg (mg)'	(b) (4) Danuel Hamlin (b) (4)	31 Oct 2020 17:50:54

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
	(b) (4)	
User entered empty.	Daniel Hamlin (b) (4)	31 Oct 2020 17:50:54
	(b) (4)	
	(b) (4)	

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'once daily (QD)'	(b) (4) Danuel Hamlin (b) (4)	31 Oct 2020 17:50:54
	(b) (4)	
	(b) (4)	

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
	(b) (4)	
User entered empty.	Daniel Hamlin (b) (4)	31 Oct 2020 17:50:54
	(b) (4)	
	(b) (4)	

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Oral (ORAL)'	(b) (4) Danuel Hamlin (b) (4)	31 Oct 2020 17:50:54
	[REDACTED]	
	[REDACTED]	

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
	(b) (4)	
User entered empty.	Daniel Hamlin (b) (4)	31 Oct 2020 17:50:54
	(b) (4)	
	(b) (4)	

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	08 Nov 2020 06:11:55
User entered '23 Oct 2020' reason for change: Data Entry Error	Danuel Hamlin (b) (4)	08 Nov 2020 06:11:55
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	31 Oct 2020 17:50:54
User entered empty.	Danuel Hamlin (b) (4)	31 Oct 2020 17:50:54

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
	(b) (4)	
User entered '0'	Daniel Hamlin (b) (4)	31 Oct 2020 17:50:54
	(b) (4)	
	(b) (4)	

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	31 Oct 2020 17:50:54

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
	(b) (4)	
User entered empty.	Daniel Hamlin (b) (4)	31 Oct 2020 17:50:54

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:43:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	31 Oct 2020 17:50:54
	(b) (4)	
	(b) (4)	

US3462374

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:43:38**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	31 Oct 2020 17:50:54

---

US3462374

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:43:38**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	31 Oct 2020 17:50:54

---

US3462374

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:43:38**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Oct 2020 17:50:54

---

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
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)	08 Nov 2020 06:18:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Nov 2020 06:18:26
Data point term sent to Coder User entered 'Tylenol'	System Danuel Hamlin (b) (4)	08 Nov 2020 06:18:16 08 Nov 2020 06:17:24

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:17:24

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the 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 or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 21:21:27
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. 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 or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' answered with 'Confirmed, this event occurred <7 days after the first dosing visit, the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria' (Site from DM).		11 Jan 2021 17:55:58

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:38

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. 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 or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM). User entered 'Injection Site Pain'	(b) (4), (b) (6) [REDACTED]	11 Jan 2021 11:39:14
	Daniel Hamlin (b) (4) [REDACTED]	08 Nov 2020 06:17:24

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered '650'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:17:24

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'mg (mg)'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:17:24

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:17:24

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'once daily (QD)'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:17:24

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:17:24

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Oral (ORAL)'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:17:24

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered empty.	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:17:24

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered '27 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:17:24

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered '0'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:17:24

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'No (N)'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:17:24

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered '27 Aug 2020'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:17:24

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:20
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Yes (Y)'	(b) (4) Danuel Hamlin (b) (4)	08 Nov 2020 06:17:24

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:20
User entered '1'	System	08 Nov 2020 06:17:24

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:20
User entered '1'	System	08 Nov 2020 06:17:24

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:43:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:20
User entered '804 (804)'	System	08 Nov 2020 06:17:24

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	02 Feb 2021 20:10:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	02 Feb 2021 20:10:32
Data point term sent to Coder	System	02 Feb 2021 20:09:26
User entered 'Ibuprofen'	(b) (4), (b) (6)	02 Feb 2021 20:09:21

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:09:21

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Covid-19'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:09:21

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered '200'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:09:21

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:09:21

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:09:21

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:09:21

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:09:21

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:09:21

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:09:21

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered '01 Jan 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:09:21

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:09:21

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:09:21

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered '03 Jan 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:09:21

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:21
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Mar 2021 19:26:10
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' (Site from DM). Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' answered with 'updated' (Site from DM). Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 10:34:53  04 Mar 2021 19:10:13  04 Mar 2021 19:09:55
User entered 'No (N)' reason for change: Data Entry Error		04 Mar 2021 19:09:55
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' (Site from DM). User signature succeeded.		01 Mar 2021 10:06:35
	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 20:09:21

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:21
User entered empty.	System	02 Feb 2021 20:09:21

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:21
User entered empty.	System	02 Feb 2021 20:09:21

US3462374

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:43:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:49:21
User entered empty.	System	02 Feb 2021 20:09:21

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:46
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'USA-US093-2021-MRNA-1273-P301000002'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:43
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'No (N)'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:41
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'No (N)'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:40
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'No (N)'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:38
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'No (N)'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:36
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'No (N)'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:34
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'No (N)'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:26
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'No (N)'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:24
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'Edward'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:23
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'Kerwin'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:20
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:09:41
User entered 'US'	System	08 Jan 2021 17:35:13

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered '2'	(b) (4)	10 Feb 2021 18:10:18
User entered '1'	System	08 Jan 2021 17:35:13

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:46
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'USA-US093-2021-MRNA-1273-P301000002'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:43
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'No (N)'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:41
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'No (N)'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:40
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'No (N)'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:38
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'No (N)'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:36
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'No (N)'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:34
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'No (N)'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:26
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'No (N)'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 16:02:24
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'Edward'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:23
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'Kerwin'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:20
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:09:41
User entered 'US'	System	08 Jan 2021 17:35:13

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered '2'	(b) (4)	10 Feb 2021 18:10:18
User entered '1'	System	08 Jan 2021 17:35:13

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:43:38

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:53
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered '08/Jan/2021 17:35'	(b) (4) System	08 Jan 2021 17:35:13

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:43:38

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:54
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:09:41
User entered '1'		08 Jan 2021 17:35:13

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:46
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'USA-US093-2021-MRNA-1273-P301000002'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:43
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'No (N)'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:41
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'No (N)'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:40
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'No (N)'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:38
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'No (N)'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:36
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'No (N)'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:34
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'No (N)'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:26
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'No (N)'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:24
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'Edward'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:23
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Jan 2021 17:35:06
User entered 'Kerwin'	System	08 Jan 2021 17:34:43

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:20
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:09:41
User entered 'US'	System	08 Jan 2021 17:35:13

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 11 Aug 2021 22:43:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered '2'	(b) (4)	10 Feb 2021 18:10:18
User entered '1'	System	08 Jan 2021 17:35:13

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:43:38

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:02:58
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered '10/Feb/2021 12:10'	(b) (4) System	10 Feb 2021 18:10:18

US3462374

Folder: SAE USA-US093-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:43:38

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:13:18
DataPoint Un-verified.		13 Apr 2021 16:03:01
DataPoint Verified.		01 Apr 2021 22:38:15
User signature succeeded.	Gregg Lucksinger (b) (4)	19 Feb 2021 20:40:29
User entered 'I'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:10:18