

US3272291 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:18:19

All time stamps listed in this document are displayed in GMT

US3272291

Form: Participant Creation

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

---

[Participant ID](#)

US3272291

---

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

---

---

US3272291

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 15:09:27

Generated On: 11 Aug 2021 22:18:19

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

Visit date (dd MMM yyyy)	22 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
------------	------

US3272291

Folder: Screening

Form: Demographics

Data signed: (b) (4) 09 Apr 2021 15:09:26

Generated On: 11 Aug 2021 22:18:19

Date of Birth (MMM yyyy)	(b) (6) 1992
Age	27
Age Units	YEARS
Age (Derived)	28
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

US3272291

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 09 Apr 2021 15:09:26

Generated On: 11 Aug 2021 22:18:19

Date of Informed Consent ( <i>dd MMM yyyy</i> )	22 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3272291

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 09 Apr 2021 15:09:27

Generated On: 11 Aug 2021 22:18:19

---

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

---

US3272291

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 09 Apr 2021 15:09:27

Generated On: 11 Aug 2021 22:18:19

Were any significant conditions reported?

Yes ☒  
No ☐

US3272291

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 09 Apr 2021 15:09:27

Generated On: 11 Aug 2021 22:18:19

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



US3272291

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 15:09:27

Generated On: 11 Aug 2021 22:18:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 AUG 2020
Time of assessment (00:00-23:59)	15:17 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 15:17
Height (xxx.x)	177.2 cm
Weight (xxx.x)	113.2 kg
BMI (xxx.x)	36.05114 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3272291

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 15:09:27

Generated On: 11 Aug 2021 22:18:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 AUG 2020

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

US3272291

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Apr 2021 15:09:27

Generated On: 11 Aug 2021 22:18:19

---

**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

US3272291

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Apr 2021 15:09:27

Generated On: 11 Aug 2021 22:18:19

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

US3272291

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

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

Visit date (dd MMM yyyy)	22 AUG 2020
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
------------	--------

US3272291

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

What was the date of randomization? (dd MMM yyyy) 22 AUG 2020

What was the participant's randomization number? 107541

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 ☒

US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Height	ND - Not Done
Weight	ND - Not Done

US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 AUG 2020
Time of assessment (00:00-23:59)	15:17 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 15:17
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG



US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 AUG 2020
Time of assessment (00:00-23:59)	17:01 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 17:01
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3272291

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 AUG 2020

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

US3272291

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

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) 22 AUG 2020

What was the treatment time? (00:00-23:59) 16:27 (24 HR)

Treatment Date and Time (derived) 22 AUG 2020 16:27

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

US3272291

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 22 AUG 2020

Collection time (00:00-23:59) 15:17 (24 HR)

Collection date and time (derived) 22 AUG 2020 15:17

US3272291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Collection date (dd MMM yyyy)			22 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:31	22 AUG 2020 15:31
Nasopharyngeal Swab 2	No		

US3272291

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 17:07

PC Open Date & Time

22 AUG 2020 16:47

PC Close Date & Time

22 AUG 2020 19:17

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

**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 97.6 °F

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

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

PC Time Stamp	22 AUG 2020 20:24
PC Open Date & Time	22 AUG 2020 20:12
PC Close Date & Time	23 AUG 2020 11:59



US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:18:19

---

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 20:52

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

25 AUG 2020 05:31

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 19:22

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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 02:48

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 22:28

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:18:19

---

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

29 AUG 2020 08:38

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 17:08

PC Open Date & Time

22 AUG 2020 16:47

PC Close Date & Time

22 AUG 2020 19:17

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

**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

22 AUG 2020 20:26

PC Open Date & Time

22 AUG 2020 20:12

PC Close Date & Time

23 AUG 2020 11:59



US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 20:53

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 19:27

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:18:19

**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

25 AUG 2020 19:23

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 02:49

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 22:29

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 08:39

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

**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 ☐

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

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

No ☒

Yes ☐

PC Time stamp	22 AUG 2020 17:09
PC Open Date & Time	22 AUG 2020 16:47
PC Close Date & Time	22 AUG 2020 19:17



US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

**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 ☐

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

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

No ☒

Yes ☐

PC Time stamp	22 AUG 2020 20:26
PC Open Date & Time	22 AUG 2020 20:12
PC Close Date & Time	23 AUG 2020 11:59

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:18:19

**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 ☒

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:18:19

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 20:54
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:18:19

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

44 of 2134

EAB) (1725)

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:18:19

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 19:28
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:18:19

**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 ☒

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:18:19

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 19:24
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59



US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:18:19

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 ☒

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:18:19

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 02:49
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:18:19

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 ☒

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:18:19

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 22:30
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:18:19

**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 ☒

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:18:19

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 08:39
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3272291

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 00:19

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3272291

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:18:19

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 AUG 2020 00:19
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59



US3272291

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272291

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272291

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3272291

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272291

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3272291

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272291

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 23:36:19

Generated On: 11 Aug 2021 22:18:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3272291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Apr 2021 23:36:19

Generated On: 11 Aug 2021 22:18:19

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	16:01 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 16:01
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG



US3272291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 23:36:19

Generated On: 11 Aug 2021 22:18:19

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	17:24 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 17:24
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3272291

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 23:36:19

Generated On: 11 Aug 2021 22:18:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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

US3272291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 23:36:19

Generated On: 11 Aug 2021 22:18:19

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) 23 SEP 2020

What was the treatment time? (00:00-23:59) 16:52 (24 HR)

Treatment Date and Time (derived) 23 SEP 2020 16:52

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

What was the frequency of the study treatment dosing? ONCE

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

US3272291

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 23:36:19

Generated On: 11 Aug 2021 22:18:19

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 SEP 2020

Collection time (00:00-23:59)

16:21 (24 HR)

Collection date and time (derived)

23 SEP 2020 16:21

US3272291

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Apr 2021 23:36:19

Generated On: 11 Aug 2021 22:18:19

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:15	23 SEP 2020 16:15
Nasopharyngeal Swab 2	No		

US3272291

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:36:19

Generated On: 11 Aug 2021 22:18:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

**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

98.1 °F

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

Yes ☐  
No ☒

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

PC Time Stamp 23 SEP 2020 17:27

PC Open Date & Time 23 SEP 2020 17:12

PC Close Date & Time 23 SEP 2020 19:42

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	23 SEP 2020 20:53
PC Open Date & Time	23 SEP 2020 20:37
PC Close Date & Time	24 SEP 2020 11:59



US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 23:43

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:18:19

---

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 07:10

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:18:19

---

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 23:18

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:18:19

---

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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 SEP 2020 23:22

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 05:40

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 21:50

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 17:27

PC Open Date & Time

23 SEP 2020 17:12

PC Close Date & Time

23 SEP 2020 19:42

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

**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

23 SEP 2020 20:46

PC Open Date & Time

23 SEP 2020 20:37

PC Close Date & Time

24 SEP 2020 11:59



US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 23:43

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 07:10

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:18:19

**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

26 SEP 2020 23:12

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 23:22

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 05:41

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 21:50

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

**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 ☐

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 17:28
PC Open Date & Time	23 SEP 2020 17:12
PC Close Date & Time	23 SEP 2020 19:42



US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

**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 ☐

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 20:49
PC Open Date & Time	23 SEP 2020 20:37
PC Close Date & Time	24 SEP 2020 11:59

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:18:19

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

90 of 2134

EAB) (1725)

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:18:19

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 23:44
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:18:19

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 ☒

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:18:19

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 07:11
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:18:19

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 ☒

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:18:19

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 23:15
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59



US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:18:19

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 ☒

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:18:19

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 23:23
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:18:19

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 ☒

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:18:19

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 05:41
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:18:19

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

100 of 2134

EAB) (1725)

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:18:19

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 21:51
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3272291

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3272291

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3272291

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 07 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3272291

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272291

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3272291

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272291

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 23:36:19

Generated On: 11 Aug 2021 22:18:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3272291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 23:36:19

Generated On: 11 Aug 2021 22:18:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 OCT 2020
Time of assessment (00:00-23:59)	16:02 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 16:02
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3272291

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 23:36:19

Generated On: 11 Aug 2021 22:18:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 OCT 2020

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

US3272291

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 23:36:19

Generated On: 11 Aug 2021 22:18:19

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

Collection date (dd MMM yyyy)	21 OCT 2020
-------------------------------	-------------

Collection time (00:00-23:59)	16:11 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	21 OCT 2020 16:11
------------------------------------	-------------------



US3272291

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:36:19

Generated On: 11 Aug 2021 22:18:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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	22 OCT 2020 10:05:32
Patient Cloud Open Date & Time	22 OCT 2020 00:01
Patient Cloud Close Date & Time	26 OCT 2020 23:59

US3272291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 OCT 2020 10:47:49

Patient Cloud Open Date & Time

29 OCT 2020 00:01

Patient Cloud Close Date & Time

02 NOV 2020 23:59

US3272291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 NOV 2020 16:20:05
Patient Cloud Open Date & Time	05 NOV 2020 00:01
Patient Cloud Close Date & Time	09 NOV 2020 23:59

US3272291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 NOV 2020 12:16:32
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 15:45:09
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59



US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 DEC 2020 06:06:07

Patient Cloud Open Date & Time

30 NOV 2020 00:01

Patient Cloud Close Date & Time

04 DEC 2020 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 DEC 2020 02:44:10
Patient Cloud Open Date & Time	07 DEC 2020 00:01
Patient Cloud Close Date & Time	11 DEC 2020 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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	16 DEC 2020 12:38:14
Patient Cloud Open Date & Time	14 DEC 2020 00:01
Patient Cloud Close Date & Time	18 DEC 2020 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

---

Date and time of submission

---

<a href="#">Patient Cloud Open Date &amp; Time</a>	21 DEC 2020 00:01
--	-------------------

---

<a href="#">Patient Cloud Close Date &amp; Time</a>	25 DEC 2020 23:59
---	-------------------

---

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 DEC 2020 21:55:32
Patient Cloud Open Date & Time	28 DEC 2020 00:01
Patient Cloud Close Date & Time	01 JAN 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 JAN 2021 12:05:26

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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 <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 JAN 2021 18:35:45
Patient Cloud Open Date & Time	11 JAN 2021 00:01
Patient Cloud Close Date & Time	15 JAN 2021 23:59



US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
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 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"/>
Date and time of submission	18 JAN 2021 05:44:08
Patient Cloud Open Date & Time	18 JAN 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
128 of 2134	

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

---

[Patient Cloud Close Date & Time](#)

22 JAN 2021 23:59

---

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 JAN 2021 14:18:56
Patient Cloud Open Date & Time	25 JAN 2021 00:01
Patient Cloud Close Date & Time	29 JAN 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 FEB 2021 20:23:24
Patient Cloud Open Date & Time	01 FEB 2021 00:01
Patient Cloud Close Date & Time	05 FEB 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 FEB 2021 20:04:21

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 FEB 2021 05:08:39
Patient Cloud Open Date & Time	15 FEB 2021 00:01
Patient Cloud Close Date & Time	19 FEB 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 FEB 2021 10:16:03
Patient Cloud Open Date & Time	22 FEB 2021 00:01
Patient Cloud Close Date & Time	26 FEB 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 MAR 2021 21:03:19
Patient Cloud Open Date & Time	01 MAR 2021 00:01
Patient Cloud Close Date & Time	05 MAR 2021 23:59



US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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	10 MAR 2021 19:00:32
Patient Cloud Open Date & Time	08 MAR 2021 00:01
Patient Cloud Close Date & Time	12 MAR 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**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

15 MAR 2021 00:01:43

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 MAR 2021 17:25:54

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 05:22:19

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 05:40:53

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 APR 2021 07:48:26
Patient Cloud Open Date & Time	12 APR 2021 00:01
Patient Cloud Close Date & Time	16 APR 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**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

19 APR 2021 05:37:30

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 00:01:28

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59



US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

[Patient Cloud Close Date & Time](#)

07 MAY 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

10 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

14 MAY 2021 23:59

---

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

24 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

28 MAY 2021 23:59

---



US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

07 JUN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

11 JUN 2021 23:59

---

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

[Patient Cloud Close Date & Time](#)

18 JUN 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59



US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

28 JUN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

---

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

05 JUL 2021 00:01

---

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

---

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 JUL 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	19 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 JUL 2021 23:59



US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

02 AUG 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

06 AUG 2021 23:59

---

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

09 AUG 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

13 AUG 2021 23:59

---

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

16 AUG 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

20 AUG 2021 23:59

---



US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 SEP 2021 23:59



US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**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 ☐

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

20 SEP 2021 00:01

---

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

---

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**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 ☐

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 OCT 2021 23:59



US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 OCT 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**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 ☐

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 OCT 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**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 ☐

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

---

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

---



US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

15 NOV 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

19 NOV 2021 23:59

---

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

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

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

29 NOV 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

03 DEC 2021 23:59

---

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 DEC 2021 23:59



US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

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 ☐

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

[Patient Cloud Close Date & Time](#)

17 DEC 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

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

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

24 DEC 2021 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

---

Date and time of submission

<a href="#">Patient Cloud Open Date &amp; Time</a>	27 DEC 2021 00:01
--	-------------------

<a href="#">Patient Cloud Close Date &amp; Time</a>	31 DEC 2021 23:59
---	-------------------

---

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**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 ☐

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59



US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59



US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

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

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**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 ☐

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

TIMEPOINT	DAY 551
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59



US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

[Patient Cloud Close Date & Time](#)

18 MAR 2022 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**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 ☐

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59



US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2022 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**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 ☐

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59



US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

02 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

---

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**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 ☐

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

23 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

27 MAY 2022 23:59

---



US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**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 ☐

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**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 ☐

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

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

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59



US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**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 ☐

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

27 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

01 JUL 2022 23:59

---

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2022 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2022 23:59



US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

25 JUL 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

29 JUL 2022 23:59

---

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

01 AUG 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

05 AUG 2022 23:59

---

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2022 23:59



US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 AUG 2022 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

12 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

---



US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**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 ☐

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

26 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

---

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**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 ☐

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

03 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

---

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2022 23:59



US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

**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 ☐

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

17 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

21 OCT 2022 23:59

---

US3272291

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3272291**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 OCT 2022 23:59

US3272291

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:18:19

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		05 MAR 2021 18:12:50

US3272291

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

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*

US3272291

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272291

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3272291

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272291

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3272291

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272291

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

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*

US3272291

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272291

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 23:36:19

Generated On: 11 Aug 2021 22:18:19

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

Visit date (dd MMM yyyy)	13 MAR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

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

US3272291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 23:36:19

Generated On: 11 Aug 2021 22:18:19

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) \_\_\_\_\_

US3272291

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 23:36:19

Generated On: 11 Aug 2021 22:18:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 MAR 2021

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



US3272291

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 23:36:19

Generated On: 11 Aug 2021 22:18:19

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 MAR 2021

Collection time (00:00-23:59)

11:08 (24 HR)

Collection date and time (derived)

13 MAR 2021 11:08

US3272291

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:36:19

Generated On: 11 Aug 2021 22:18:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3272291**

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

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

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*

**US3272291**

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

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

Date of Contact	10 DEC 2020
Time of Contact	13:00
Date and Time of Contact (derived)	10 DEC 2020 13:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input checked="" type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

Symptom Day

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

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

	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 DEC 2020
------	-------------

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

O2 Saturation	99 %
---------------	------

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

Temperature	36.5 C
-------------	--------

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

Cough	None <input 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

318 of 2134

EAB) (1725)

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

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



US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

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

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

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"/>

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

	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 DEC 2020
------	-------------

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

O2 Saturation	99 %
---------------	------

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

Temperature	98.3 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

322 of 2134

EAB) (1725)

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

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

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

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

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

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"/>

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

	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 DEC 2020	
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)

326 of 2134

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

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



US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

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

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

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"/>

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

330 of 2134

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

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

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

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

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

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"/>

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
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 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)

334 of 2134

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

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



US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

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

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

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"/>

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

	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 DEC 2020
------	-------------

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

O2 Saturation	100 %
---------------	-------

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

Temperature	98.2 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"/>

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

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

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

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

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

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"/>

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

	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 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

342 of 2134

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

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



US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

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

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

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"/>

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.2 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)

346 of 2134

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

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

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

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

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

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"/>

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

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

Date	18 DEC 2020
------	-------------

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

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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)

350 of 2134

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

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



US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

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

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

Date of Visit 10 DEC 2020

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

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

Date of Test 10 DEC 2020

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

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

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

If yes, provide lab information below

Lab/ Institution Test Performed \_\_\_\_\_

CLIA Certified? Yes ☐  
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3272291

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	12 DEC 2020
Day 5	Yes	14 DEC 2020
Day 7	Yes	16 DEC 2020
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

US3272291

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3272291

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 DEC 2020
Time of assessment (00:00-23:59)	17:25 (24 HR)
Vital Signs Date and Time (derived)	10 DEC 2020 17:25
Height (xxx.x)	177.2 cm
Weight (xxx.x)	113.2 kg
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3272291

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 DEC 2020

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

US3272291

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

10 DEC 2020

US3272291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

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

Visit date (dd MMM yyyy)	14 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
------------	---------------



US3272291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Date of updated informed consent ( <i>dd MMM yyyy</i> )	14 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	14 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3272291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3272291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	17:08 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 17:08
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3272291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	18:11 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 18:11
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3272291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 JAN 2021

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

US3272291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 14 JAN 2021

What was the treatment time? (00:00-23:59) 17:37 (24 HR)

Treatment Date and Time (derived) 14 JAN 2021 17:37

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

US3272291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

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

Collection date (dd MMM yyyy)	14 JAN 2021
-------------------------------	-------------

Collection time (00:00-23:59)	16:51 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	14 JAN 2021 16:51
------------------------------------	-------------------

US3272291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	16:57
Collection Date and Time (derived)	14 JAN 2021 16:57



US3272291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272291

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272291

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3272291

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

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

Visit date (dd MMM yyyy)	08 FEB 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
------------	-------

US3272291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 FEB 2021
Time of assessment (00:00-23:59)	16:08 (24 HR)
Vital Signs Date and Time (derived)	08 FEB 2021 16:08
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3272291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

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

US3272291

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 FEB 2021

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

US3272291

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

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 FULL BODY HIVES AFTER 1ST DOSE- SEE AE

What was the study treatment? (Unblinded) \_\_\_\_\_

What was the treatment date? (dd MMM yyyy) \_\_\_\_\_

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

Treatment Date and Time (derived) \_\_\_\_\_

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

What was the frequency of the study treatment dosing? \_\_\_\_\_

What was the route of administration for the study treatment? \_\_\_\_\_



US3272291

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272291

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3272291

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272291

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3272291

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 MAR 2021
Time of assessment (00:00-23:59)	10:56 (24 HR)
Vital Signs Date and Time (derived)	13 MAR 2021 10:56
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3272291

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 MAR 2021

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

US3272291

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 23:36:18

Generated On: 11 Aug 2021 22:18:19

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

Collection date (dd MMM yyyy)	13 MAR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	11:08 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	13 MAR 2021 11:08
------------------------------------	-------------------

US3272291

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---



US3272291

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 14 Apr 2021 19:03:34

Generated On: 11 Aug 2021 22:18:19

AEID

Adverse event

HIVES, FULLY BODY

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

15 JAN 2021

Start time (00:00-23:59)

15:00 (24 HR)

AE start date and time (derived)

15 JAN 2021 15:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

18 JAN 2021

End time (00:00-23:59)

12:00 (24 HR)

AE End Date and Time (derived)

18 JAN 2021 12:00

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

384 of 2134

EAB) (1725)

US3272291

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 14 Apr 2021 19:03:34

Generated On: 11 Aug 2021 22:18:19

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 type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3272291

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 14 Apr 2021 19:03:34

Generated On: 11 Aug 2021 22:18:19

AEID	
Adverse event	SUSPECTED 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 type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	08 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

386 of 2134

US3272291

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 14 Apr 2021 19:03:34

Generated On: 11 Aug 2021 22:18:19

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3272291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 15:09:26

Generated On: 11 Aug 2021 22:18:19

---

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

---

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

---

US3272291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 15:09:26

Generated On: 11 Aug 2021 22:18:19

Name of Medication DIPHENHYDRAMINE

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

Dose per administration 25

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)

389 of 2134

US3272291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 15:09:26

Generated On: 11 Aug 2021 22:18:19

	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)		21 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3272291

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 15:09:26

Generated On: 11 Aug 2021 22:18:19

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---



US3272291

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 29 Apr 2021 23:35:34

Generated On: 11 Aug 2021 22:18:19

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

US3272291

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:18:19

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 ☐

Audit

US3272291 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

**US3272291**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 22:18:19**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
User entered 'US3272291'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 20:54:09

US3272291

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:18:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'Yes (Y)'	Ashley Bell (b) (4)	22 Aug 2020 22:00:25

US3272291

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:18:19

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '22 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 20:54:10

US3272291

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:18:19

[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 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'Clinic (Clinic)'	Ashley Bell (b) (4)	22 Aug 2020 22:00:25

**US3272291**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User entered 'SCRN'	System	22 Aug 2020 22:00:25



US3272291

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:18:19

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered (b) (6) 1992'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 20:54:11

**US3272291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:18:19**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '27'	Ashley Bell (b) (4)	22 Aug 2020 22:00:34

**US3272291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:18:19**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User entered 'YEARS'	System	22 Aug 2020 22:00:34

**US3272291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:18:19**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User entered '28'	System	22 Aug 2020 22:00:48

US3272291

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:18:19

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'Male (M)'	Ashley Bell (b) (4)	22 Aug 2020 22:00:34

US3272291

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:18:19

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Ashley Bell (b) (4)	22 Aug 2020 22:00:34

**US3272291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:18:19**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'I'	Ashley Bell (b) (4)	22 Aug 2020 22:00:34

**US3272291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:18:19**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '0'	Ashley Bell (b) (4)	22 Aug 2020 22:00:34



**US3272291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:18:19**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '0'	Ashley Bell (b) (4)	22 Aug 2020 22:00:34

US3272291

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:18:19

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '0'	Ashley Bell (b) (4)	22 Aug 2020 22:00:34

**US3272291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:18:19**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '0'	Ashley Bell (b) (4)	22 Aug 2020 22:00:34

**US3272291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:18:19**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '0'	Ashley Bell (b) (4)	22 Aug 2020 22:00:34

US3272291

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:18:19

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered empty.	Ashley Bell (b) (4)	22 Aug 2020 22:00:34

**US3272291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:18:19**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '0'	Ashley Bell (b) (4)	22 Aug 2020 22:00:34

**US3272291**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:18:19**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '0'	Ashley Bell (b) (4)	22 Aug 2020 22:00:34

US3272291

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:18:19

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '22 Aug 2020'	Ashley Bell (b) (4)	22 Aug 2020 22:00:48



**US3272291**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:18:19**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User entered 'Aug 2020'	System	22 Aug 2020 22:00:48

**US3272291**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:18:19**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User entered '2020'	System	22 Aug 2020 22:00:48

US3272291

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:18:19

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'Amendment 2 (2)'	Ashley Bell (b) (4)	22 Aug 2020 22:00:48

US3272291

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:18:19

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'Yes (Y)'	Ashley Bell (b) (4)	22 Aug 2020 22:00:48

**US3272291**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:18:19**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered empty.	Ashley Bell (b) (4)	22 Aug 2020 22:00:48

US3272291

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:18:19

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered empty.	Ashley Bell (b) (4)	22 Aug 2020 22:00:48

**US3272291**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:18:19**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'No (N)'	Ashley Bell (b) (4)	22 Aug 2020 22:00:48

US3272291

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:18:19

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 20:54:10



US3272291

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:18:19

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User entered 'I'	System	22 Aug 2020 22:00:52

US3272291

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:18:19

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'Yes (Y)'	Ashley Bell (b) (4)	22 Aug 2020 22:00:52

US3272291

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:18:19

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'Yes (Y)'	Kayla Flege (b) (4)	21 Nov 2020 23:40:53
	(b) (4)	

US3272291

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:18:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	21 Nov 2020 23:58:05
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Nov 2020 23:58:05
	(b) (4)	
Data point term sent to Coder	System	21 Nov 2020 23:41:51
User entered 'insomnia'	Kayla Flege (b) (4)	21 Nov 2020 23:41:14
	(b) (4)	

**US3272291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'un Jul 2020'	Kayla Flege (b) (4)	21 Nov 2020 23:41:14
	(b) (4)	

US3272291

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:18:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '0'	Kayla Flege (b) (4)	21 Nov 2020 23:41:14
	(b) (4)	

**US3272291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'Yes (Y)'	Kayla Flege (b) (4)	21 Nov 2020 23:41:14
	(b) (4)	

**US3272291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:18:19**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered empty.	Kayla Flege (b) (4)	21 Nov 2020 23:41:14
	(b) (4)	



**US3272291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '0'	Kayla Flege (b) (4)	21 Nov 2020 23:41:14
	(b) (4)	

**US3272291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User entered 'Jul 2020'	System	21 Nov 2020 23:41:14

**US3272291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User entered '2020'	System	21 Nov 2020 23:41:14

**US3272291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User entered empty.	System	21 Nov 2020 23:41:14

**US3272291**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User entered empty.	System	21 Nov 2020 23:41:14

US3272291

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'Yes (Y)'	Kayla Flege (b) (4)	21 Nov 2020 23:42:05
	(b) (4)	

US3272291

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '22 Aug 2020'	Kayla Flege (b) (4)	21 Nov 2020 23:42:05
	(b) (4)	

**US3272291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '15:17'	Kayla Flege (b) (4)	21 Nov 2020 23:42:05
	(b) (4)	



**US3272291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User entered '22 Aug 2020 15:17'	System	21 Nov 2020 23:42:05

US3272291

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:19

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '177.2' cm	Kayla Flege (b) (4)	21 Nov 2020 23:42:05
	(b) (4)	
DataPoint set to visible.	System	22 Aug 2020 22:00:52

US3272291

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:19

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '113.2' kg	Kayla Flege (b) (4)	21 Nov 2020 23:42:05
	(b) (4)	
DataPoint set to visible.	System	22 Aug 2020 22:00:52

**US3272291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User entered '36.05114'	System	21 Nov 2020 23:42:05
DataPoint set to visible.	System	22 Aug 2020 22:00:52

**US3272291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User entered 'kg/m2'	System	21 Nov 2020 23:42:05
DataPoint set to visible.	System	22 Aug 2020 22:00:52

US3272291

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered missing code ND - Not Done.	Kayla Flege (b) (4)	21 Nov 2020 23:42:05
	(b) (4)	

US3272291

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered empty.	Kayla Flege (b) (4)	21 Nov 2020 23:42:05
	(b) (4)	

**US3272291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered empty.	Kayla Flege (b) (4)	21 Nov 2020 23:42:05
	(b) (4)	



**US3272291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered missing code ND - Not Done.	Kayla Flege (b) (4)	21 Nov 2020 23:42:05
	(b) (4)	

**US3272291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User entered 'bpm'	System	21 Nov 2020 23:42:05

US3272291

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered missing code ND - Not Done.	Kayla Flege (b) (4)	21 Nov 2020 23:42:05
	(b) (4)	

US3272291

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User entered 'breaths/min'	System	21 Nov 2020 23:42:05

US3272291

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered missing code ND - Not Done.	Kayla Flege (b) (4)	21 Nov 2020 23:42:05
	(b) (4)	

US3272291

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User entered 'mmHg'	System	21 Nov 2020 23:42:05

US3272291

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered missing code ND - Not Done.	Kayla Flege (b) (4)	21 Nov 2020 23:42:05
	(b) (4)	

US3272291

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User entered 'mmHg'	System	21 Nov 2020 23:42:05



**US3272291**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17

US3272291

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:19

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17

US3272291

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:18:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'Yes (Y)'	Kayla Flege (b) (4)	21 Nov 2020 23:42:40
	(b) (4)	

US3272291

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:18:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '22 Aug 2020'	Kayla Flege (b) (4)	21 Nov 2020 23:42:40
	(b) (4)	

US3272291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:19

**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 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'No (N)'	Kayla Flege (b) (4)	21 Nov 2020 23:43:33
	(b) (4)	

US3272291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:19

**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 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'No (N)'	Kayla Flege (b) (4)	21 Nov 2020 23:43:33
	(b) (4)	

US3272291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:19

**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 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'No (N)'	Kayla Flege (b) (4)	21 Nov 2020 23:43:33
	(b) (4)	

US3272291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:19

**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 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'Yes (Y)'	Kayla Flege (b) (4)	21 Nov 2020 23:43:33
	(b) (4)	



US3272291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:19

[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 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'No (N)'	Kayla Flege (b) (4)	21 Nov 2020 23:43:33
	(b) (4)	

US3272291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:19

[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 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'No (N)'	Kayla Flege (b) (4)	21 Nov 2020 23:43:33
	(b) (4)	

US3272291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:19

**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 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'No (N)'	Kayla Flege (b) (4)	21 Nov 2020 23:43:33
	(b) (4)	

US3272291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:19

**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 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'No (N)'	Kayla Flege (b) (4)	21 Nov 2020 23:43:33
	(b) (4)	

US3272291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:19

[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 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'No (N)'	Kayla Flege (b) (4)	21 Nov 2020 23:43:33
	(b) (4)	

US3272291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:19

**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 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'No (N)'	Kayla Flege (b) (4)	21 Nov 2020 23:43:33
	(b) (4)	

US3272291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:19

**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 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'No (N)'	Kayla Flege (b) (4)	21 Nov 2020 23:43:33
	(b) (4)	

US3272291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:19

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'No (N)'	Kayla Flege (b) (4)	21 Nov 2020 23:43:33
	(b) (4)	



US3272291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:19

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered empty.	Kayla Flege (b) (4)	21 Nov 2020 23:43:33
	(b) (4)	

US3272291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:19

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '0'	Kayla Flege (b) (4)	21 Nov 2020 23:43:33
	(b) (4)	

US3272291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:19

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '0'	Kayla Flege (b) (4)	21 Nov 2020 23:43:33
	(b) (4)	

US3272291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:19

**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 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '0'	Kayla Flege (b) (4)	21 Nov 2020 23:43:33
	(b) (4)	

US3272291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:19

[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 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '0'	Kayla Flege (b) (4)	21 Nov 2020 23:43:33
	(b) (4)	

US3272291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:19

**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 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '0'	Kayla Flege (b) (4)	21 Nov 2020 23:43:33
	(b) (4)	

US3272291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:19

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'I'	Kayla Flege (b) (4)	21 Nov 2020 23:43:33
	(b) (4)	

US3272291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:19

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '0'	Kayla Flege (b) (4)	21 Nov 2020 23:43:33
	(b) (4)	



US3272291

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:18:19

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:38:17
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered empty.	Kayla Flege (b) (4)	21 Nov 2020 23:43:33
	(b) (4)	

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 18:48:51

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '22 Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 18:48:51

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	27 Aug 2020 18:48:51

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User entered 'VISIT1'	System	27 Aug 2020 18:48:51

US3272291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:18:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '22 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 20:54:18

US3272291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:18:19

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '107541'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 20:54:18

US3272291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:18:19

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 20:54:18



US3272291

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:18:19

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)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 18:49:10

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:18:19**

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)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 18:49:10

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:18:19**

[Severe obesity \(body mass index > or = 40kg/m2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 18:49:10

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:18:19**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 18:49:10

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:18:19**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 18:49:10

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:18:19**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 22:17:17
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:39:26
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:22:07

US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:18:19

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User closed query 'Per CDM: If a participant is screened, enrolled, randomized, and dosed on the same day then 'Height/Weight' should be recorded as "Not done" at this visit (V1D1). Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 08:06:53
Query 'Per CDM: If a participant is screened, enrolled, randomized, and dosed on the same day then 'Height/Weight' should be recorded as "Not done" at this visit (V1D1). Please review and update accordingly.' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	07 Oct 2020 19:22:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	07 Oct 2020 19:22:08
User opened query 'Per CDM: If a participant is screened, enrolled, randomized, and dosed on the same day then 'Height/Weight' should be recorded as "Not done" at this visit (V1D1). Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 07:58:24
User entered '177.2' cm	(b) (4), (b) (6)	27 Aug 2020 18:51:28

US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:18:19

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	07 Oct 2020 19:22:08
User entered '113.2' kg	(b) (4), (b) (6)	27 Aug 2020 18:51:28



US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:18:19

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User closed query 'Per CDM: If a participant is screened, enrolled, randomized, and dosed on the same day then 'Height/Weight' should be recorded as "Not done" at this visit (V1D1). Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 08:06:53
Query 'Per CDM: If a participant is screened, enrolled, randomized, and dosed on the same day then 'Height/Weight' should be recorded as "Not done" at this visit (V1D1). Please review and update accordingly.' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	07 Oct 2020 19:22:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	07 Oct 2020 19:22:08
User opened query 'Per CDM: If a participant is screened, enrolled, randomized, and dosed on the same day then 'Height/Weight' should be recorded as "Not done" at this visit (V1D1). Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 07:58:24
User entered '177.2' cm	(b) (4), (b) (6)	27 Aug 2020 18:51:28

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:18:19**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	07 Oct 2020 19:22:08
User entered '113.2' kg	(b) (4), (b) (6)	27 Aug 2020 18:51:28

US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User accepted default value 'Pre-Dose (PREDOSE)'		27 Aug 2020 18:51:28

US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 18:51:28

US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '22 Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 18:51:28

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '15:17'	(b) (4), (b) (6)	27 Aug 2020 18:51:28

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User entered '22 Aug 2020 15:17'	System	27 Aug 2020 18:51:28

US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '36.8' C	(b) (4), (b) (6)	27 Aug 2020 18:51:28



US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Oral (Oral)'	(b) (4), (b) (6)	27 Aug 2020 18:51:28

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 18:51:28

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '61'	(b) (4), (b) (6)	27 Aug 2020 18:51:28

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User entered 'bpm'	System	27 Aug 2020 18:51:28

US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '14'	(b) (4), (b) (6)	27 Aug 2020 18:51:28

US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User entered 'breaths/min'	System	27 Aug 2020 18:51:28

US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '123'	(b) (4), (b) (6)	27 Aug 2020 18:51:28

US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User entered 'mmHg'	System	27 Aug 2020 18:51:28



US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '83'	(b) (4), (b) (6)	27 Aug 2020 18:51:28

US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User entered 'mmHg'	System	27 Aug 2020 18:51:28

US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:18:19

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User closed query 'Per CDM: If a participant is screened, enrolled, randomized, and dosed on the same day then 'Height/Weight' should be recorded as "Not done" at this visit (V1D1). Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 08:06:53
Query 'Per CDM: If a participant is screened, enrolled, randomized, and dosed on the same day then 'Height/Weight' should be recorded as "Not done" at this visit (V1D1). Please review and update accordingly.' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	07 Oct 2020 19:22:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	07 Oct 2020 19:22:08
User opened query 'Per CDM: If a participant is screened, enrolled, randomized, and dosed on the same day then 'Height/Weight' should be recorded as "Not done" at this visit (V1D1). Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 07:58:24
User entered '177.2' cm	(b) (4), (b) (6)	27 Aug 2020 18:51:28

US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:18:19

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	07 Oct 2020 19:22:08
User entered '113.2' kg	(b) (4), (b) (6)	27 Aug 2020 18:51:28

US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User accepted default value 'Post-Dose (POSTDOSE)'		27 Aug 2020 18:51:28

US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 18:51:28

US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '22 Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 18:51:28

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '17:01'	(b) (4), (b) (6)	27 Aug 2020 18:51:28



**US3272291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User entered '22 Aug 2020 17:01'	System	27 Aug 2020 18:51:28

US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '36.6' C	(b) (4), (b) (6)	27 Aug 2020 18:51:28

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Oral (Oral)'	(b) (4), (b) (6)	27 Aug 2020 18:51:28

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 18:51:28

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '68'	(b) (4), (b) (6)	27 Aug 2020 18:51:28

US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User entered 'bpm'	System	27 Aug 2020 18:51:28

US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '16'	(b) (4), (b) (6)	27 Aug 2020 18:51:28

US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User entered 'breaths/min'	System	27 Aug 2020 18:51:28



US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '120'	(b) (4), (b) (6)	27 Aug 2020 18:51:28

US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User entered 'mmHg'	System	27 Aug 2020 18:51:28

US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '78'	(b) (4), (b) (6)	27 Aug 2020 18:51:28

US3272291

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User entered 'mmHg'	System	27 Aug 2020 18:51:28

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:18:19**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 18:51:39

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:18:19**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '22 Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 18:51:39

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:18:19**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	Ashley Bell (b) (4)	22 Aug 2020 22:01:09

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:18:19**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	Ashley Bell (b) (4)	22 Aug 2020 22:01:09



US3272291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:18:19

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)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	Ashley Bell (b) (4)	22 Aug 2020 22:01:09

US3272291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:18:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User entered 'MRNA-1273 OR PLACEBO'	System	22 Aug 2020 22:01:09

US3272291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:18:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '22 Aug 2020'	Ashley Bell (b) (4)	22 Aug 2020 22:01:09

US3272291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:18:19

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '16:27'	Ashley Bell (b) (4)	22 Aug 2020 22:01:09

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:18:19**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User entered '22 Aug 2020 16:27'	System	22 Aug 2020 22:01:09

US3272291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:18:19

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Left Arm (LEFT ARM)'	Ashley Bell (b) (4)	22 Aug 2020 22:01:09

US3272291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:18:19

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User entered 'ONCE'	System	22 Aug 2020 22:01:09

US3272291

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:18:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User entered 'INTRAMUSCULAR'	System	22 Aug 2020 22:01:09



US3272291

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:18:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 18:52:43

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:18:19**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '22 Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 18:52:43

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:18:19**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '15:17'	(b) (4), (b) (6)	27 Aug 2020 18:52:43

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:18:19**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User entered '22 Aug 2020 15:17'	System	27 Aug 2020 18:52:43

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 22:18:19**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '22 Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 18:53:10

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		27 Aug 2020 18:53:10

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 18:53:10

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:18:19**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '15:31'	(b) (4), (b) (6)	27 Aug 2020 18:53:10



**US3272291**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User entered '22 Aug 2020 15:31'	System	27 Aug 2020 18:53:10

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		27 Aug 2020 18:53:10

US3272291

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:18:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 18:53:10

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:18:19**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 18:53:10

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User entered empty.	System	27 Aug 2020 18:53:10

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 18:53:21

**US3272291**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:21:57
User entered 'I'	System	27 Aug 2020 18:53:21

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 22:01:09



US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T17:06:42', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '5c05d1a9-29a4-4b1b-83e1-535765be9433'	System	22 Aug 2020 22:07:14
User entered 'Yes (Y)'	System	22 Aug 2020 22:07:14

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T17:06:51', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '5c05d1a9-29a4-4b1b-83e1-535765be9433' User entered '97.8'	System	22 Aug 2020 22:07:14
	System	22 Aug 2020 22:07:14

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T17:07:01', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '5c05d1a9-29a4-4b1b-83e1-535765be9433'	System	22 Aug 2020 22:07:14
User entered 'No (N)'	System	22 Aug 2020 22:07:14

**US3272291**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T17:07:11', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '5c05d1a9-29a4-4b1b-83e1-535765be9433'	System	22 Aug 2020 22:07:14
User entered '22 Aug 2020 17:07'	System	22 Aug 2020 22:07:14

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '22 Aug 2020 16:47'	System	22 Aug 2020 22:01:09

**US3272291**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '22 Aug 2020 19:17'	System	22 Aug 2020 22:01:09

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 22:01:09

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T20:23:48', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '3eb4bd13-4ce5-4223-b0b7-a5c275ac5e39'	System	23 Aug 2020 01:24:12
User entered 'Yes (Y)'	System	23 Aug 2020 01:24:12



US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T20:23:57', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '3eb4bd13-4ce5-4223-b0b7-a5c275ac5e39'	System	23 Aug 2020 01:24:12
User entered '97.6'	System	23 Aug 2020 01:24:12

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T20:24:03', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '3eb4bd13-4ce5-4223-b0b7-a5c275ac5e39'	System	23 Aug 2020 01:24:12
User entered 'No (N)'	System	23 Aug 2020 01:24:12

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T20:24:09', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '3eb4bd13-4ce5-4223-b0b7-a5c275ac5e39'	System	23 Aug 2020 01:24:12
User entered '22 Aug 2020 20:24'	System	23 Aug 2020 01:24:12

**US3272291**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '22 Aug 2020 20:12'	System	22 Aug 2020 22:01:09

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 22:01:09

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered 'Day 2'	System	22 Aug 2020 22:01:09

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:18:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-23T20:52:05', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '37de78af-50db-4bfd-8b79-e0aa17e1261c'	System	24 Aug 2020 01:52:27
User entered 'Yes (Y)'	System	24 Aug 2020 01:52:27

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:18:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-23T20:52:12', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '37de78af-50db-4bfd-8b79-e0aa17e1261c'	System	24 Aug 2020 01:52:27
User entered '98.0'	System	24 Aug 2020 01:52:27



US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:18:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-23T20:52:17', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '37de78af-50db-4bfd-8b79-e0aa17e1261c'	System	24 Aug 2020 01:52:27
User entered 'No (N)'	System	24 Aug 2020 01:52:27

**US3272291**

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

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-23T20:52:23', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '37de78af-50db-4bfd-8b79-e0aa17e1261c'	System	24 Aug 2020 01:52:27
User entered '23 Aug 2020 20:52'	System	24 Aug 2020 01:52:27

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:18:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 22:01:09

**US3272291**

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

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 22:01:09

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered 'Day 3'	System	22 Aug 2020 22:01:09

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:18:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-25T05:30:56', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '4ff0faa1-ead0-48f3-9c9f-f9920b8e3f0f'	System	25 Aug 2020 10:31:34
User entered 'Yes (Y)'	System	25 Aug 2020 10:31:34

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:18:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-25T05:31:20', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '4ff0faa1-ead0-48f3-9c9f-f9920b8e3f0f'	System	25 Aug 2020 10:31:34
User entered '98.2'	System	25 Aug 2020 10:31:34

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:18:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-25T05:31:26', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '4ff0faa1-ead0-48f3-9c9f-f9920b8e3f0f'	System	25 Aug 2020 10:31:34
User entered 'No (N)'	System	25 Aug 2020 10:31:34



**US3272291**

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

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

**Generated On: 11 Aug 2021 22:18:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-25T05:31:29', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '4ff0faa1-ead0-48f3-9c9f-f9920b8e3f0f'	System	25 Aug 2020 10:31:34
User entered '25 Aug 2020 05:31'	System	25 Aug 2020 10:31:34

**US3272291**

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

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

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 22:01:09

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:18:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 22:01:09

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered 'Day 4'	System	22 Aug 2020 22:01:09

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:18:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-25T19:22:12', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '9a57055d-f2e9-48b1-8175-04c3da0637ba'	System	26 Aug 2020 00:22:37
User entered 'Yes (Y)'	System	26 Aug 2020 00:22:37

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:18:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-25T19:22:19', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '9a57055d-f2e9-48b1-8175-04c3da0637ba'	System	26 Aug 2020 00:22:37
User entered '98.8'	System	26 Aug 2020 00:22:37

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:18:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-25T19:22:23', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '9a57055d-f2e9-48b1-8175-04c3da0637ba'	System	26 Aug 2020 00:22:37
User entered 'No (N)'	System	26 Aug 2020 00:22:37

**US3272291**

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

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

**Generated On: 11 Aug 2021 22:18:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-25T19:22:30', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '9a57055d-f2e9-48b1-8175-04c3da0637ba'	System	26 Aug 2020 00:22:37
User entered '25 Aug 2020 19:22'	System	26 Aug 2020 00:22:37



US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:18:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 22:01:09

**US3272291**

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

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

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 22:01:09

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered 'Day 5'	System	22 Aug 2020 22:01:09

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:18:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T02:48:33', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'c60846bf-cb35-4492-bba4-bfffc9aea3de'	System	27 Aug 2020 07:48:53
User entered 'Yes (Y)'	System	27 Aug 2020 07:48:53

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:18:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T02:48:42', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'c60846bf-cb35-4492-bba4-bfffc9aea3de'	System	27 Aug 2020 07:48:53
User entered '98.9'	System	27 Aug 2020 07:48:53

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:18:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T02:48:47', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'c60846bf-cb35-4492-bba4-bfffc9aea3de'	System	27 Aug 2020 07:48:53
User entered 'No (N)'	System	27 Aug 2020 07:48:53

**US3272291**

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

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T02:48:50', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'c60846bf-cb35-4492-bba4-bffc9aea3de'	System	27 Aug 2020 07:48:53
User entered '27 Aug 2020 02:48'	System	27 Aug 2020 07:48:53

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:18:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 22:01:09



**US3272291**

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

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 22:01:09

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered 'Day 6'	System	22 Aug 2020 22:01:09

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:18:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T22:28:33', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'ae723a5a-112b-469b-bb17-b4b39388c983'	System	28 Aug 2020 03:28:58
User entered 'Yes (Y)'	System	28 Aug 2020 03:28:58

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:18:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T22:28:41', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'ae723a5a-112b-469b-bb17-b4b39388c983' User entered '98.3'	System	28 Aug 2020 03:28:58
	System	28 Aug 2020 03:28:58

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:18:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T22:28:48', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'ae723a5a-112b-469b-bb17-b4b39388c983'	System	28 Aug 2020 03:28:58
User entered 'No (N)'	System	28 Aug 2020 03:28:58

**US3272291**

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

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T22:28:54', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'ae723a5a-112b-469b-bb17-b4b39388c983'	System	28 Aug 2020 03:28:58
User entered '27 Aug 2020 22:28'	System	28 Aug 2020 03:28:58

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:18:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 22:01:09

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:18:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 22:01:09



US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered 'Day 7'	System	22 Aug 2020 22:01:09

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:18:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-29T08:38:31', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'fa574208-3a56-44eb-b603-5696b1b2d591'	System	29 Aug 2020 13:38:53
User entered 'Yes (Y)'	System	29 Aug 2020 13:38:53

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:18:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-29T08:38:44', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'fa574208-3a56-44eb-b603-5696b1b2d591'	System	29 Aug 2020 13:38:53
User entered '97.9'	System	29 Aug 2020 13:38:53

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:18:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-29T08:38:47', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'fa574208-3a56-44eb-b603-5696b1b2d591'	System	29 Aug 2020 13:38:53
User entered 'No (N)'	System	29 Aug 2020 13:38:53

**US3272291**

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

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-29T08:38:50', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'fa574208-3a56-44eb-b603-5696b1b2d591'	System	29 Aug 2020 13:38:53
User entered '29 Aug 2020 08:38'	System	29 Aug 2020 13:38:53

US3272291

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:18:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 22:01:09

**US3272291**

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

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 22:01:09

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 22:01:09



US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T17:07:35', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'cab556b2-0369-47c0-bae6-c40d01dcbc8b'	System	22 Aug 2020 22:08:22
User entered 'None (1)'	System	22 Aug 2020 22:08:22

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T17:07:45', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'cab556b2-0369-47c0-bae6-c40d01dcbc8b'	System	22 Aug 2020 22:08:22
User entered 'No (N)'	System	22 Aug 2020 22:08:22

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T17:07:52', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'cab556b2-0369-47c0-bae6-c40d01dcbc8b'	System	22 Aug 2020 22:08:22
User entered 'No (N)'	System	22 Aug 2020 22:08:22

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T17:08:05', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'cab556b2-0369-47c0-bae6-c40d01dcbc8b'	System	22 Aug 2020 22:08:22
User entered 'None (1)'	System	22 Aug 2020 22:08:22

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T17:08:16', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'cab556b2-0369-47c0-bae6-c40d01dcbc8b'	System	22 Aug 2020 22:08:22
User entered '22 Aug 2020 17:08'	System	22 Aug 2020 22:08:22

**US3272291**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '22 Aug 2020 16:47'	System	22 Aug 2020 22:01:09

**US3272291**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '22 Aug 2020 19:17'	System	22 Aug 2020 22:01:09

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 22:01:09



US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T20:24:27', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '3ababbca-28fc-4cc3-8fce-8f6ffad7deec'	System	23 Aug 2020 01:26:08
User entered 'None (1)'	System	23 Aug 2020 01:26:08

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T20:24:30', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '3ababbca-28fc-4cc3-8fce-8f6ffad7deec'	System	23 Aug 2020 01:26:08
User entered 'No (N)'	System	23 Aug 2020 01:26:08

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T20:24:39', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '3ababbca-28fc-4cc3-8fce-8f6ffad7deec'	System	23 Aug 2020 01:26:08
User entered 'No (N)'	System	23 Aug 2020 01:26:08

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T20:24:53', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '3ababbca-28fc-4cc3-8fce-8f6ffad7deec'	System	23 Aug 2020 01:26:08
User entered 'None (1)'	System	23 Aug 2020 01:26:08

**US3272291**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T20:26:01', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '3ababbca-28fc-4cc3-8fce-8f6ffad7deec'	System	23 Aug 2020 01:26:08
User entered '22 Aug 2020 20:26'	System	23 Aug 2020 01:26:08

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '22 Aug 2020 20:12'	System	22 Aug 2020 22:01:09

**US3272291**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 22:01:09

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered 'Day 2'	System	22 Aug 2020 22:01:09



US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-23T20:52:31', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '4ff7b4d9-80ec-43a0-b2dd-df4585183cba'	System	24 Aug 2020 01:53:35
User entered 'None (1)'	System	24 Aug 2020 01:53:35

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:18:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-23T20:52:43', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '4ff7b4d9-80ec-43a0-b2dd-df4585183cba'	System	24 Aug 2020 01:53:35
User entered 'No (N)'	System	24 Aug 2020 01:53:35

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:18:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-23T20:52:54', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '4ff7b4d9-80ec-43a0-b2dd-df4585183cba'	System	24 Aug 2020 01:53:35
User entered 'No (N)'	System	24 Aug 2020 01:53:35

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-23T20:53:22', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '4ff7b4d9-80ec-43a0-b2dd-df4585183cba'	System	24 Aug 2020 01:53:35
User entered 'None (1)'	System	24 Aug 2020 01:53:35

**US3272291**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-23T20:53:29', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '4ff7b4d9-80ec-43a0-b2dd-df4585183cba'	System	24 Aug 2020 01:53:35
User entered '23 Aug 2020 20:53'	System	24 Aug 2020 01:53:35

**US3272291**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 22:01:09

**US3272291**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 22:01:09

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered 'Day 3'	System	22 Aug 2020 22:01:09



US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-24T19:26:25', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '408ff935-6ad5-4aab-bbc8-41834d495417'	System	25 Aug 2020 00:27:21
User entered 'None (1)'	System	25 Aug 2020 00:27:21

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:18:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-24T19:26:32', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '408ff935-6ad5-4aab-bbc8-41834d495417'	System	25 Aug 2020 00:27:21
User entered 'No (N)'	System	25 Aug 2020 00:27:21

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:18:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-24T19:26:42', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '408ff935-6ad5-4aab-bbc8-41834d495417'	System	25 Aug 2020 00:27:21
User entered 'No (N)'	System	25 Aug 2020 00:27:21

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-24T19:27:02', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '408ff935-6ad5-4aab-bbc8-41834d495417'	System	25 Aug 2020 00:27:21
User entered 'None (1)'	System	25 Aug 2020 00:27:21

**US3272291**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-24T19:27:17', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '408ff935-6ad5-4aab-bbc8-41834d495417'	System	25 Aug 2020 00:27:21
User entered '24 Aug 2020 19:27'	System	25 Aug 2020 00:27:21

**US3272291**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 22:01:09

**US3272291**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 22:01:09

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered 'Day 4'	System	22 Aug 2020 22:01:09



US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-25T19:22:43', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'a57b378c-4907-44c9-8a12-e9978fa458fb'	System	26 Aug 2020 00:23:21
User entered 'None (1)'	System	26 Aug 2020 00:23:21

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:18:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-25T19:22:45', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'a57b378c-4907-44c9-8a12-e9978fa458fb'	System	26 Aug 2020 00:23:21
User entered 'No (N)'	System	26 Aug 2020 00:23:21

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:18:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-25T19:22:48', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'a57b378c-4907-44c9-8a12-e9978fa458fb'	System	26 Aug 2020 00:23:21
User entered 'No (N)'	System	26 Aug 2020 00:23:21

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-25T19:23:07', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'a57b378c-4907-44c9-8a12-e9978fa458fb'	System	26 Aug 2020 00:23:21
User entered 'None (1)'	System	26 Aug 2020 00:23:21

**US3272291**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-25T19:23:15', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'a57b378c-4907-44c9-8a12-e9978fa458fb'	System	26 Aug 2020 00:23:21
User entered '25 Aug 2020 19:23'	System	26 Aug 2020 00:23:21

**US3272291**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 22:01:09

**US3272291**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 22:01:09

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered 'Day 5'	System	22 Aug 2020 22:01:09



US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T02:49:05', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '26ab25db-6d5d-4ca2-beeb-c0dea71f33cf'	System	27 Aug 2020 07:49:22
User entered 'None (1)'	System	27 Aug 2020 07:49:22

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:18:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T02:49:09', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '26ab25db-6d5d-4ca2-beeb-c0dea71f33cf'	System	27 Aug 2020 07:49:22
User entered 'No (N)'	System	27 Aug 2020 07:49:22

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:18:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T02:49:13', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '26ab25db-6d5d-4ca2-beeb-c0dea71f33cf'	System	27 Aug 2020 07:49:22
User entered 'No (N)'	System	27 Aug 2020 07:49:22

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T02:49:15', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '26ab25db-6d5d-4ca2-beeb-c0dea71f33cf'	System	27 Aug 2020 07:49:22
User entered 'None (1)'	System	27 Aug 2020 07:49:22

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:18:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T02:49:18', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '26ab25db-6d5d-4ca2-beeb-c0dea71f33cf'	System	27 Aug 2020 07:49:22
User entered '27 Aug 2020 02:49'	System	27 Aug 2020 07:49:22

**US3272291**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 22:01:09

**US3272291**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 22:01:09

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered 'Day 6'	System	22 Aug 2020 22:01:09



US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T22:28:58', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'd3b264f3-8fa7-427e-a0b2-43760a0fc294'	System	28 Aug 2020 03:29:29
User entered 'None (1)'	System	28 Aug 2020 03:29:29

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:18:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T22:29:02', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'd3b264f3-8fa7-427e-a0b2-43760a0fc294'	System	28 Aug 2020 03:29:29
User entered 'No (N)'	System	28 Aug 2020 03:29:29

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:18:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T22:29:09', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'd3b264f3-8fa7-427e-a0b2-43760a0fc294'	System	28 Aug 2020 03:29:29
User entered 'No (N)'	System	28 Aug 2020 03:29:29

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T22:29:22', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'd3b264f3-8fa7-427e-a0b2-43760a0fc294'	System	28 Aug 2020 03:29:29
User entered 'None (1)'	System	28 Aug 2020 03:29:29

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:18:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T22:29:25', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'd3b264f3-8fa7-427e-a0b2-43760a0fc294'	System	28 Aug 2020 03:29:29
User entered '27 Aug 2020 22:29'	System	28 Aug 2020 03:29:29

**US3272291**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 22:01:09

**US3272291**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 22:01:09

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered 'Day 7'	System	22 Aug 2020 22:01:09



US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-29T08:38:56', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'b431a8d4-ad27-40cc-88bc-6a587a624e6d'	System	29 Aug 2020 13:39:09
User entered 'None (1)'	System	29 Aug 2020 13:39:09

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:18:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-29T08:38:59', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'b431a8d4-ad27-40cc-88bc-6a587a624e6d'	System	29 Aug 2020 13:39:09
User entered 'No (N)'	System	29 Aug 2020 13:39:09

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:18:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-29T08:39:01', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'b431a8d4-ad27-40cc-88bc-6a587a624e6d'	System	29 Aug 2020 13:39:09
User entered 'No (N)'	System	29 Aug 2020 13:39:09

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-29T08:39:03', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'b431a8d4-ad27-40cc-88bc-6a587a624e6d'	System	29 Aug 2020 13:39:09
User entered 'None (1)'	System	29 Aug 2020 13:39:09

**US3272291**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-29T08:39:05', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'b431a8d4-ad27-40cc-88bc-6a587a624e6d'	System	29 Aug 2020 13:39:09
User entered '29 Aug 2020 08:39'	System	29 Aug 2020 13:39:09

US3272291

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:18:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 22:01:09

**US3272291**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 22:01:09

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 22:01:09



**US3272291**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:18:19**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T17:08:35', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '570f414a-4b9e-40af-8461-5c1aa887423c'	System	22 Aug 2020 22:09:44
User entered 'None (0)'	System	22 Aug 2020 22:09:44

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T17:08:44', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '570f414a-4b9e-40af-8461-5c1aa887423c'	System	22 Aug 2020 22:09:44
User entered 'None (0)'	System	22 Aug 2020 22:09:44

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T17:08:49', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '570f414a-4b9e-40af-8461-5c1aa887423c'	System	22 Aug 2020 22:09:44
User entered 'None (0)'	System	22 Aug 2020 22:09:44

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T17:08:55', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '570f414a-4b9e-40af-8461-5c1aa887423c'	System	22 Aug 2020 22:09:44
User entered 'None (0)'	System	22 Aug 2020 22:09:44

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T17:09:03', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '570f414a-4b9e-40af-8461-5c1aa887423c'	System	22 Aug 2020 22:09:44
User entered 'None (0)'	System	22 Aug 2020 22:09:44

**US3272291**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:18:19**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T17:09:15', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '570f414a-4b9e-40af-8461-5c1aa887423c'	System	22 Aug 2020 22:09:44
User entered 'No interference with activity (1)'	System	22 Aug 2020 22:09:44

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T17:09:33', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '570f414a-4b9e-40af-8461-5c1aa887423c'	System	22 Aug 2020 22:09:44
User entered 'No (N)'	System	22 Aug 2020 22:09:44

**US3272291**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T17:09:38', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '570f414a-4b9e-40af-8461-5c1aa887423c'	System	22 Aug 2020 22:09:44
User entered '22 Aug 2020 17:09'	System	22 Aug 2020 22:09:44



**US3272291**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '22 Aug 2020 16:47'	System	22 Aug 2020 22:01:09

**US3272291**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '22 Aug 2020 19:17'	System	22 Aug 2020 22:01:09

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 22:01:09

**US3272291**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:18:19**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T20:26:11', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'cbaffe34-6cf7-4958-9e4d-97bd9e0442ae'	System	23 Aug 2020 01:26:54
User entered 'None (0)'	System	23 Aug 2020 01:26:54

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T20:26:15', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'cbaffe34-6cf7-4958-9e4d-97bd9e0442ae'	System	23 Aug 2020 01:26:54
User entered 'None (0)'	System	23 Aug 2020 01:26:54

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T20:26:23', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'cbaffe34-6cf7-4958-9e4d-97bd9e0442ae'	System	23 Aug 2020 01:26:54
User entered 'None (0)'	System	23 Aug 2020 01:26:54

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T20:26:28', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'cbaffe34-6cf7-4958-9e4d-97bd9e0442ae'	System	23 Aug 2020 01:26:54
User entered 'None (0)'	System	23 Aug 2020 01:26:54

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T20:26:31', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'cbaffe34-6cf7-4958-9e4d-97bd9e0442ae'	System	23 Aug 2020 01:26:54
User entered 'None (0)'	System	23 Aug 2020 01:26:54



US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T20:26:34', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'cbaffe34-6cf7-4958-9e4d-97bd9e0442ae'	System	23 Aug 2020 01:26:54
User entered 'None (0)'	System	23 Aug 2020 01:26:54

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T20:26:46', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'cbaffe34-6cf7-4958-9e4d-97bd9e0442ae'	System	23 Aug 2020 01:26:54
User entered 'No (N)'	System	23 Aug 2020 01:26:54

**US3272291**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-22T20:26:50', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'cbaffe34-6cf7-4958-9e4d-97bd9e0442ae'	System	23 Aug 2020 01:26:54
User entered '22 Aug 2020 20:26'	System	23 Aug 2020 01:26:54

**US3272291**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '22 Aug 2020 20:12'	System	22 Aug 2020 22:01:09

**US3272291**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 22:01:09

**US3272291**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered 'Day 2'	System	22 Aug 2020 22:01:09

**US3272291**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:18:19**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-23T20:53:34', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'bed82351-ee52-4776-95a1-7c4f5e93b682'	System	24 Aug 2020 01:54:29
User entered 'None (0)'	System	24 Aug 2020 01:54:29

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:18:19

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-23T20:53:50', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'bed82351-ee52-4776-95a1-7c4f5e93b682'	System	24 Aug 2020 01:54:29
User entered 'None (0)'	System	24 Aug 2020 01:54:29



US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:18:19

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-23T20:53:53', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'bed82351-ee52-4776-95a1-7c4f5e93b682'	System	24 Aug 2020 01:54:29
User entered 'None (0)'	System	24 Aug 2020 01:54:29

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:18:19

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-23T20:53:59', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'bed82351-ee52-4776-95a1-7c4f5e93b682'	System	24 Aug 2020 01:54:29
User entered 'None (0)'	System	24 Aug 2020 01:54:29

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:18:19

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-23T20:54:03', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'bed82351-ee52-4776-95a1-7c4f5e93b682'	System	24 Aug 2020 01:54:29
User entered 'None (0)'	System	24 Aug 2020 01:54:29

**US3272291**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:18:19**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-23T20:54:05', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'bed82351-ee52-4776-95a1-7c4f5e93b682'	System	24 Aug 2020 01:54:29
User entered 'None (0)'	System	24 Aug 2020 01:54:29

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-23T20:54:16', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'bed82351-ee52-4776-95a1-7c4f5e93b682'	System	24 Aug 2020 01:54:29
User entered 'No (N)'	System	24 Aug 2020 01:54:29

**US3272291**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-23T20:54:23', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'bed82351-ee52-4776-95a1-7c4f5e93b682'	System	24 Aug 2020 01:54:29
User entered '23 Aug 2020 20:54'	System	24 Aug 2020 01:54:29

**US3272291**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 22:01:09

**US3272291**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 22:01:09



**US3272291**

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

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

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered 'Day 3'	System	22 Aug 2020 22:01:09

**US3272291**

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

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

**Generated On: 11 Aug 2021 22:18:19**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-24T19:27:27', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '58e1ee22-19ed-4a7d-965d-5a2dcec618d8'	System	25 Aug 2020 00:28:14
User entered 'None (0)'	System	25 Aug 2020 00:28:14

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:18:19

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-24T19:27:30', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '58e1ee22-19ed-4a7d-965d-5a2dcec618d8'	System	25 Aug 2020 00:28:14
User entered 'None (0)'	System	25 Aug 2020 00:28:14

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:18:19

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-24T19:27:33', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '58e1ee22-19ed-4a7d-965d-5a2dcec618d8'	System	25 Aug 2020 00:28:14
User entered 'None (0)'	System	25 Aug 2020 00:28:14

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:18:19

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-24T19:27:36', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '58e1ee22-19ed-4a7d-965d-5a2dcec618d8'	System	25 Aug 2020 00:28:14
User entered 'None (0)'	System	25 Aug 2020 00:28:14

**US3272291**

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

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

**Generated On: 11 Aug 2021 22:18:19**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-24T19:27:52', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '58e1ee22-19ed-4a7d-965d-5a2dcec618d8'	System	25 Aug 2020 00:28:14
User entered 'None (0)'	System	25 Aug 2020 00:28:14

**US3272291**

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

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

**Generated On: 11 Aug 2021 22:18:19**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-24T19:27:55', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '58e1ee22-19ed-4a7d-965d-5a2dcec618d8'	System	25 Aug 2020 00:28:14
User entered 'None (0)'	System	25 Aug 2020 00:28:14

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-24T19:28:02', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '58e1ee22-19ed-4a7d-965d-5a2dcec618d8'	System	25 Aug 2020 00:28:14
User entered 'No (N)'	System	25 Aug 2020 00:28:14



**US3272291**

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

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

**Generated On: 11 Aug 2021 22:18:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-24T19:28:06', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '58e1ee22-19ed-4a7d-965d-5a2dcec618d8'	System	25 Aug 2020 00:28:14
User entered '24 Aug 2020 19:28'	System	25 Aug 2020 00:28:14

**US3272291**

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

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

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 22:01:09

**US3272291**

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

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

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 22:01:09

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered 'Day 4'	System	22 Aug 2020 22:01:09

**US3272291**

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

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

**Generated On: 11 Aug 2021 22:18:19**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-25T19:23:19', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '1207a629-0e95-4efb-9993-3f304db4461b'	System	26 Aug 2020 00:24:46
User entered 'None (0)'	System	26 Aug 2020 00:24:46

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:18:19

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-25T19:23:21', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '1207a629-0e95-4efb-9993-3f304db4461b'	System	26 Aug 2020 00:24:46
User entered 'None (0)'	System	26 Aug 2020 00:24:46

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:18:19

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-25T19:23:24', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '1207a629-0e95-4efb-9993-3f304db4461b'	System	26 Aug 2020 00:24:46
User entered 'None (0)'	System	26 Aug 2020 00:24:46

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:18:19

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-25T19:23:28', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '1207a629-0e95-4efb-9993-3f304db4461b' User entered 'None (0)'	System	26 Aug 2020 00:24:46
	System	26 Aug 2020 00:24:46



US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:18:19

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-25T19:23:31', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '1207a629-0e95-4efb-9993-3f304db4461b'	System	26 Aug 2020 00:24:46
User entered 'None (0)'	System	26 Aug 2020 00:24:46

**US3272291**

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

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

**Generated On: 11 Aug 2021 22:18:19**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-25T19:23:34', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '1207a629-0e95-4efb-9993-3f304db4461b'	System	26 Aug 2020 00:24:46
User entered 'None (0)'	System	26 Aug 2020 00:24:46

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-25T19:24:36', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '1207a629-0e95-4efb-9993-3f304db4461b'	System	26 Aug 2020 00:24:46
User entered 'No (N)'	System	26 Aug 2020 00:24:46

**US3272291**

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

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

**Generated On: 11 Aug 2021 22:18:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-25T19:24:42', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '1207a629-0e95-4efb-9993-3f304db4461b'	System	26 Aug 2020 00:24:46
User entered '25 Aug 2020 19:24'	System	26 Aug 2020 00:24:46

**US3272291**

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

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

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 22:01:09

**US3272291**

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

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

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 22:01:09

**US3272291**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered 'Day 5'	System	22 Aug 2020 22:01:09

**US3272291**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:18:19**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T02:49:22', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '1c0162ba-77d3-43e2-be11-da5b0dc1eb6e'	System	27 Aug 2020 07:50:04
User entered 'None (0)'	System	27 Aug 2020 07:50:04



**US3272291**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:18:19**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T02:49:24', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '1c0162ba-77d3-43e2-be11-da5b0dc1eb6e'	System	27 Aug 2020 07:50:04
User entered 'None (0)'	System	27 Aug 2020 07:50:04

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:18:19

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T02:49:27', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '1c0162ba-77d3-43e2-be11-da5b0dc1eb6e'	System	27 Aug 2020 07:50:04
User entered 'None (0)'	System	27 Aug 2020 07:50:04

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:18:19

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T02:49:31', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '1c0162ba-77d3-43e2-be11-da5b0dc1eb6e'	System	27 Aug 2020 07:50:04
User entered 'None (0)'	System	27 Aug 2020 07:50:04

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:18:19

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T02:49:34', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '1c0162ba-77d3-43e2-be11-da5b0dc1eb6e'	System	27 Aug 2020 07:50:04
User entered 'None (0)'	System	27 Aug 2020 07:50:04

**US3272291**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:18:19**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T02:49:37', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '1c0162ba-77d3-43e2-be11-da5b0dc1eb6e'	System	27 Aug 2020 07:50:04
User entered 'None (0)'	System	27 Aug 2020 07:50:04

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T02:49:51', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '1c0162ba-77d3-43e2-be11-da5b0dc1eb6e'	System	27 Aug 2020 07:50:04
User entered 'No (N)'	System	27 Aug 2020 07:50:04

**US3272291**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T02:49:59', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '1c0162ba-77d3-43e2-be11-da5b0dc1eb6e'	System	27 Aug 2020 07:50:04
User entered '27 Aug 2020 02:49'	System	27 Aug 2020 07:50:04

**US3272291**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 22:01:09



**US3272291**

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

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 22:01:09

**US3272291**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered 'Day 6'	System	22 Aug 2020 22:01:09

**US3272291**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:18:19**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T22:30:08', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '98119a0b-5447-41a3-b6d4-13978b827ad8'	System	28 Aug 2020 03:30:27
User entered 'No interference with activity (1)'	System	28 Aug 2020 03:30:27

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:18:19

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T22:29:37', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '98119a0b-5447-41a3-b6d4-13978b827ad8'	System	28 Aug 2020 03:30:27
User entered 'None (0)'	System	28 Aug 2020 03:30:27

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:18:19

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T22:29:39', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '98119a0b-5447-41a3-b6d4-13978b827ad8'	System	28 Aug 2020 03:30:27
User entered 'None (0)'	System	28 Aug 2020 03:30:27

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:18:19

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T22:29:41', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '98119a0b-5447-41a3-b6d4-13978b827ad8'	System	28 Aug 2020 03:30:27
User entered 'None (0)'	System	28 Aug 2020 03:30:27

**US3272291**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:18:19**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T22:29:46', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '98119a0b-5447-41a3-b6d4-13978b827ad8'	System	28 Aug 2020 03:30:27
User entered 'None (0)'	System	28 Aug 2020 03:30:27

**US3272291**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:18:19**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T22:29:49', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '98119a0b-5447-41a3-b6d4-13978b827ad8'	System	28 Aug 2020 03:30:27
User entered 'None (0)'	System	28 Aug 2020 03:30:27



US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T22:29:53', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '98119a0b-5447-41a3-b6d4-13978b827ad8'	System	28 Aug 2020 03:30:27
User entered 'No (N)'	System	28 Aug 2020 03:30:27

**US3272291**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-27T22:30:21', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '98119a0b-5447-41a3-b6d4-13978b827ad8'	System	28 Aug 2020 03:30:27
User entered '27 Aug 2020 22:30'	System	28 Aug 2020 03:30:27

**US3272291**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 22:01:09

**US3272291**

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

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 22:01:09

**US3272291**

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

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered 'Day 7'	System	22 Aug 2020 22:01:09

**US3272291**

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

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:18:19**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-29T08:39:12', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '93ef36a3-438b-4e22-bec5-67c4d06418b6'	System	29 Aug 2020 13:39:42
User entered 'No interference with activity (1)'	System	29 Aug 2020 13:39:42

**US3272291**

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

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:18:19**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-29T08:39:16', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '93ef36a3-438b-4e22-bec5-67c4d06418b6'	System	29 Aug 2020 13:39:42
User entered 'None (0)'	System	29 Aug 2020 13:39:42

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:18:19

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-29T08:39:18', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '93ef36a3-438b-4e22-bec5-67c4d06418b6'	System	29 Aug 2020 13:39:42
User entered 'None (0)'	System	29 Aug 2020 13:39:42



US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:18:19

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-29T08:39:19', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '93ef36a3-438b-4e22-bec5-67c4d06418b6'	System	29 Aug 2020 13:39:42
User entered 'None (0)'	System	29 Aug 2020 13:39:42

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:18:19

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-29T08:39:21', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '93ef36a3-438b-4e22-bec5-67c4d06418b6'	System	29 Aug 2020 13:39:42
User entered 'None (0)'	System	29 Aug 2020 13:39:42

**US3272291**

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

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:18:19**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-29T08:39:24', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '93ef36a3-438b-4e22-bec5-67c4d06418b6'	System	29 Aug 2020 13:39:42
User entered 'None (0)'	System	29 Aug 2020 13:39:42

US3272291

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-29T08:39:33', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '93ef36a3-438b-4e22-bec5-67c4d06418b6'	System	29 Aug 2020 13:39:42
User entered 'No (N)'	System	29 Aug 2020 13:39:42

**US3272291**

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

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-29T08:39:37', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '93ef36a3-438b-4e22-bec5-67c4d06418b6'	System	29 Aug 2020 13:39:42
User entered '29 Aug 2020 08:39'	System	29 Aug 2020 13:39:42

**US3272291**

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

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 22:01:09

**US3272291**

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

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 22:01:09

**US3272291**

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

**Form: Headache\_Day(8)**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	28 Aug 2020 03:30:27
User entered 'Day 8'	System	28 Aug 2020 03:30:27



US3272291

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 22:18:19

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-30T00:19:25', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'a90169d9-061a-46bc-9561-4acc7e70a839'	System	30 Aug 2020 05:19:40
User entered 'None (0)'	System	30 Aug 2020 05:19:40

**US3272291**

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

**Form: Headache\_Day(8)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-30T00:19:32', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'a90169d9-061a-46bc-9561-4acc7e70a839'	System	30 Aug 2020 05:19:40
User entered '30 Aug 2020 00:19'	System	30 Aug 2020 05:19:40

**US3272291**

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

**Form: Headache\_Day(8)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 03:30:27

**US3272291**

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

**Form: Headache\_Day(8)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 03:30:27

**US3272291**

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

**Form: Medical Attention\_Day(8)**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	28 Aug 2020 03:30:27
User entered 'Day 8'	System	28 Aug 2020 03:30:27

US3272291

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-30T00:19:41', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '406b63ae-018f-412d-8c44-8c8502e8df8a'	System	30 Aug 2020 05:19:53
User entered 'No (N)'	System	30 Aug 2020 05:19:53

**US3272291**

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

**Form: Medical Attention\_Day(8)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-08-30T00:19:45', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '406b63ae-018f-412d-8c44-8c8502e8df8a'	System	30 Aug 2020 05:19:53
User entered '30 Aug 2020 00:19'	System	30 Aug 2020 05:19:53

**US3272291**

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

**Form: Medical Attention\_Day(8)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 03:30:27



**US3272291**

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

**Form: Medical Attention\_Day(8)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 03:30:27

**US3272291**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:54:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 15:15:45

**US3272291**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:54:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '31 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 15:15:45

**US3272291**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:54:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	31 Aug 2020 15:15:45

**US3272291**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:54:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 15:15:45

US3272291

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:54:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 15:16:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 15:16:08
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 15:16:08
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 15:15:49
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 15:15:49

**US3272291**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:54:04
User entered '1'	System	31 Aug 2020 15:16:08
User entered empty.	System	31 Aug 2020 15:15:49

**US3272291**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 21:15:36



US3272291

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '05 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 21:15:36

**US3272291**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Sep 2020 21:15:36

US3272291

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:18:19

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 21:15:36

US3272291

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 21:15:39

**US3272291**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:03:26
User entered 'I'	System	14 Sep 2020 21:15:39

**US3272291**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:31:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 21:15:50

**US3272291**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:31:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '12 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 21:15:50

**US3272291**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:31:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Sep 2020 21:15:50



**US3272291**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:31:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 21:15:50

**US3272291**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:31:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 21:15:54

**US3272291**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:31:14
User entered 'I'	System	14 Sep 2020 21:15:54

**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 17:59:43

**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '23 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 17:59:43

**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Sep 2020 17:59:43

**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User entered 'VISIT2'	System	24 Sep 2020 17:59:43

**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User accepted default value 'Pre-Dose (PREDOSE)'		24 Sep 2020 18:00:38



US3272291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 18:00:38

US3272291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '23 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 18:00:38

**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '16:01'	(b) (4), (b) (6)	24 Sep 2020 18:00:38

**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User entered '23 Sep 2020 16:01'	System	24 Sep 2020 18:00:38

US3272291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '36.8' C	(b) (4), (b) (6)	24 Sep 2020 18:00:38

US3272291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Oral (Oral)'	(b) (4), (b) (6)	24 Sep 2020 18:00:38

**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 18:00:38

**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '75'	(b) (4), (b) (6)	24 Sep 2020 18:00:38



**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User entered 'bpm'	System	24 Sep 2020 18:00:38

**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '20'	(b) (4), (b) (6)	24 Sep 2020 18:00:38

US3272291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User entered 'breaths/min'	System	24 Sep 2020 18:00:38

US3272291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '136'	(b) (4), (b) (6)	24 Sep 2020 18:00:38

US3272291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User entered 'mmHg'	System	24 Sep 2020 18:00:38

US3272291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '89'	(b) (4), (b) (6)	24 Sep 2020 18:00:38

US3272291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User entered 'mmHg'	System	24 Sep 2020 18:00:38

US3272291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User accepted default value 'Post-Dose (POSTDOSE)'		24 Sep 2020 18:00:38



US3272291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 18:00:38

US3272291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '23 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 18:00:38

**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '17:24'	(b) (4), (b) (6)	24 Sep 2020 18:00:38

**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User entered '23 Sep 2020 17:24'	System	24 Sep 2020 18:00:38

US3272291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '36.7' C	(b) (4), (b) (6)	24 Sep 2020 18:00:38

US3272291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Oral (Oral)'	(b) (4), (b) (6)	24 Sep 2020 18:00:38

**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 18:00:38

**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '74'	(b) (4), (b) (6)	24 Sep 2020 18:00:38



**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User entered 'bpm'	System	24 Sep 2020 18:00:38

US3272291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '18'	(b) (4), (b) (6)	24 Sep 2020 18:00:38

US3272291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User entered 'breaths/min'	System	24 Sep 2020 18:00:38

US3272291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '132'	(b) (4), (b) (6)	24 Sep 2020 18:00:38

US3272291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User entered 'mmHg'	System	24 Sep 2020 18:00:38

US3272291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '81'	(b) (4), (b) (6)	24 Sep 2020 18:00:38

US3272291

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User entered 'mmHg'	System	24 Sep 2020 18:00:38

**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:18:19**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 18:00:43



US3272291

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:18:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '23 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 18:00:43

US3272291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 22:17:40

**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:18:19**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 22:17:40

US3272291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:19

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)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 22:17:40

US3272291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 22:17:40

US3272291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '23 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 22:17:40

US3272291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:19

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '16:52'	(b) (4), (b) (6)	23 Sep 2020 22:17:40

US3272291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:19

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User entered '23 Sep 2020 16:52'	System	23 Sep 2020 22:17:40



US3272291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:19

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	23 Sep 2020 22:17:40

US3272291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:19

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User entered 'ONCE'	System	23 Sep 2020 22:17:40

US3272291

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 22:17:40

US3272291

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:18:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 18:01:06

US3272291

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:18:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '23 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 18:01:06

**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:18:19**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '16:21'	(b) (4), (b) (6)	24 Sep 2020 18:01:06

**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:18:19**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User entered '23 Sep 2020 16:21'	System	24 Sep 2020 18:01:06

**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 22:18:19**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '23 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 18:01:15



**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	24 Sep 2020 18:01:15

**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 18:01:15

**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:18:19**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '16:15'	(b) (4), (b) (6)	24 Sep 2020 18:01:15

**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User entered '23 Sep 2020 16:15'	System	24 Sep 2020 18:01:15

**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		24 Sep 2020 18:01:15

**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 18:01:15

**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:18:19**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 18:01:15

**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User entered empty.	System	24 Sep 2020 18:01:15



**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 18:01:18

**US3272291**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:25:36
User entered '1'	System	24 Sep 2020 18:01:18

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	23 Sep 2020 22:17:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T17:26:46', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '82e45e1b-c6af-4f88-9a8c-8b7bb2f56562'	System	23 Sep 2020 22:27:13
User entered 'Yes (Y)'	System	23 Sep 2020 22:27:13

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T17:26:53', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '82e45e1b-c6af-4f88-9a8c-8b7bb2f56562'	System	23 Sep 2020 22:27:13
User entered '98.1'	System	23 Sep 2020 22:27:13

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T17:27:01', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '82e45e1b-c6af-4f88-9a8c-8b7bb2f56562'	System	23 Sep 2020 22:27:13
User entered 'No (N)'	System	23 Sep 2020 22:27:13

**US3272291**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T17:27:08', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '82e45e1b-c6af-4f88-9a8c-8b7bb2f56562'	System	23 Sep 2020 22:27:13
User entered '23 Sep 2020 17:27'	System	23 Sep 2020 22:27:13

**US3272291**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '23 Sep 2020 17:12'	System	23 Sep 2020 22:17:40



**US3272291**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '23 Sep 2020 19:42'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	23 Sep 2020 22:17:40
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T20:53:02', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '5fd62ff3-16de-49ba-b73e-515fefb930cf'	System	24 Sep 2020 01:53:24
User entered 'Yes (Y)'	System	24 Sep 2020 01:53:24

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T20:53:09', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '5fd62ff3-16de-49ba-b73e-515fefb930cf' User entered '98.3'	System	24 Sep 2020 01:53:24
	System	24 Sep 2020 01:53:24

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T20:53:14', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '5fd62ff3-16de-49ba-b73e-515fefb930cf'	System	24 Sep 2020 01:53:24
User entered 'No (N)'	System	24 Sep 2020 01:53:24

**US3272291**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T20:53:18', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '5fd62ff3-16de-49ba-b73e-515fefb930cf' User entered '23 Sep 2020 20:53'	System	24 Sep 2020 01:53:24
	System	24 Sep 2020 01:53:24

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '23 Sep 2020 20:37'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 22:17:40



US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	23 Sep 2020 22:17:40
User entered 'Day 2'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:18:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-24T23:42:46', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'be11f4c8-5bde-4a9e-9478-407f3a6e5890'	System	25 Sep 2020 04:43:18
User entered 'Yes (Y)'	System	25 Sep 2020 04:43:18

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:18:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-24T23:43:02', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'be11f4c8-5bde-4a9e-9478-407f3a6e5890' User entered '97.0'	System	25 Sep 2020 04:43:18
	System	25 Sep 2020 04:43:18

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:18:19

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-24T23:43:06', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'be11f4c8-5bde-4a9e-9478-407f3a6e5890'	System	25 Sep 2020 04:43:18
User entered 'No (N)'	System	25 Sep 2020 04:43:18

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-24T23:43:14', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'be11f4c8-5bde-4a9e-9478-407f3a6e5890'	System	25 Sep 2020 04:43:18
User entered '24 Sep 2020 23:43'	System	25 Sep 2020 04:43:18

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	23 Sep 2020 22:17:40
User entered 'Day 3'	System	23 Sep 2020 22:17:40



US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:18:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T07:09:39', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '7510e482-395d-4535-ad30-df019750805c'	System	26 Sep 2020 12:10:13
User entered 'Yes (Y)'	System	26 Sep 2020 12:10:13

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:18:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T07:09:54', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '7510e482-395d-4535-ad30-df019750805c'	System	26 Sep 2020 12:10:13
User entered '98.8'	System	26 Sep 2020 12:10:13

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:18:19

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T07:10:04', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '7510e482-395d-4535-ad30-df019750805c'	System	26 Sep 2020 12:10:13
User entered 'No (N)'	System	26 Sep 2020 12:10:13

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T07:10:08', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '7510e482-395d-4535-ad30-df019750805c'	System	26 Sep 2020 12:10:13
User entered '26 Sep 2020 07:10'	System	26 Sep 2020 12:10:13

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	23 Sep 2020 22:17:40
User entered 'Day 4'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:18:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T23:17:31', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '543f650b-0939-47e6-917a-4c801aea6985'	System	27 Sep 2020 04:18:26
User entered 'Yes (Y)'	System	27 Sep 2020 04:18:26



US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:18:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T23:17:40', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '543f650b-0939-47e6-917a-4c801aea6985' User entered '97.3'	System	27 Sep 2020 04:18:26
	System	27 Sep 2020 04:18:26

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:18:19

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T23:18:13', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '543f650b-0939-47e6-917a-4c801aea6985'	System	27 Sep 2020 04:18:26
User entered 'No (N)'	System	27 Sep 2020 04:18:26

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T23:18:21', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '543f650b-0939-47e6-917a-4c801aea6985'	System	27 Sep 2020 04:18:26
User entered '26 Sep 2020 23:18'	System	27 Sep 2020 04:18:26

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:18:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	23 Sep 2020 22:17:40
User entered 'Day 5'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:18:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-27T23:21:57', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'c0c04207-ce31-4587-87b5-d0aedd401f71'	System	28 Sep 2020 04:22:19
User entered 'Yes (Y)'	System	28 Sep 2020 04:22:19

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:18:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-27T23:22:06', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'c0c04207-ce31-4587-87b5-d0aedd401f71'	System	28 Sep 2020 04:22:19
User entered '97.9'	System	28 Sep 2020 04:22:19



US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:18:19

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-27T23:22:10', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'c0c04207-ce31-4587-87b5-d0aedd401f71'	System	28 Sep 2020 04:22:19
User entered 'No (N)'	System	28 Sep 2020 04:22:19

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-27T23:22:13', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'c0c04207-ce31-4587-87b5-d0aedd401f71'	System	28 Sep 2020 04:22:19
User entered '27 Sep 2020 23:22'	System	28 Sep 2020 04:22:19

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	23 Sep 2020 22:17:40
User entered 'Day 6'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:18:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T05:40:18', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '595f67fb-4280-4856-b728-dbecbbf8bdb7'	System	29 Sep 2020 10:40:48
User entered 'Yes (Y)'	System	29 Sep 2020 10:40:48

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:18:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T05:40:27', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '595f67fb-4280-4856-b728-dbecbbf8bdb7'	System	29 Sep 2020 10:40:48
User entered '98.8'	System	29 Sep 2020 10:40:48

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:18:19

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T05:40:32', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '595f67fb-4280-4856-b728-dbecbbf8bdb7'	System	29 Sep 2020 10:40:48
User entered 'No (N)'	System	29 Sep 2020 10:40:48



**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T05:40:44', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '595f67fb-4280-4856-b728-dbecbbf8bdb7'	System	29 Sep 2020 10:40:48
User entered '29 Sep 2020 05:40'	System	29 Sep 2020 10:40:48

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:18:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	23 Sep 2020 22:17:40
User entered 'Day 7'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:18:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T21:50:20', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '33f75c5d-ca46-454a-a338-ffb5676c6f9a'	System	30 Sep 2020 02:50:37
User entered 'Yes (Y)'	System	30 Sep 2020 02:50:37

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:18:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T21:50:28', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '33f75c5d-ca46-454a-a338-ffb5676c6f9a' User entered '97.6'	System	30 Sep 2020 02:50:37
	System	30 Sep 2020 02:50:37

US3272291

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:18:19

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T21:50:31', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '33f75c5d-ca46-454a-a338-ffb5676c6f9a'	System	30 Sep 2020 02:50:37
User entered 'No (N)'	System	30 Sep 2020 02:50:37

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T21:50:34', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '33f75c5d-ca46-454a-a338-ffb5676c6f9a'	System	30 Sep 2020 02:50:37
User entered '29 Sep 2020 21:50'	System	30 Sep 2020 02:50:37



**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	23 Sep 2020 22:17:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T17:27:25', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'dd1e832e-eede-43c0-98f2-e9a0854bcd'bd'	System	23 Sep 2020 22:27:58
User entered 'None (1)'	System	23 Sep 2020 22:27:58

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T17:27:34', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'dd1e832e-eede-43c0-98f2-e9a0854bcd'bd'	System	23 Sep 2020 22:27:58
User entered 'No (N)'	System	23 Sep 2020 22:27:58

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T17:27:40', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'dd1e832e-eede-43c0-98f2-e9a0854bcd'bd'	System	23 Sep 2020 22:27:58
User entered 'No (N)'	System	23 Sep 2020 22:27:58

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T17:27:51', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'dd1e832e-eede-43c0-98f2-e9a0854bcd'bd'	System	23 Sep 2020 22:27:58
User entered 'None (1)'	System	23 Sep 2020 22:27:58

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T17:27:55', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'dd1e832e-eede-43c0-98f2-e9a0854bcd'bd'	System	23 Sep 2020 22:27:58
User entered '23 Sep 2020 17:27'	System	23 Sep 2020 22:27:58



**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '23 Sep 2020 17:12'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '23 Sep 2020 19:42'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	23 Sep 2020 22:17:40
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T20:45:59', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '0e77fcc3-a8f5-4897-9894-ba8f740a78d2'	System	24 Sep 2020 01:47:04
User entered 'None (1)'	System	24 Sep 2020 01:47:04

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T20:46:03', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '0e77fcc3-a8f5-4897-9894-ba8f740a78d2'	System	24 Sep 2020 01:47:04
User entered 'No (N)'	System	24 Sep 2020 01:47:04

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T20:46:08', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '0e77fcc3-a8f5-4897-9894-ba8f740a78d2'	System	24 Sep 2020 01:47:04
User entered 'No (N)'	System	24 Sep 2020 01:47:04

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T20:46:51', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '0e77fcc3-a8f5-4897-9894-ba8f740a78d2'	System	24 Sep 2020 01:47:04
User entered 'None (1)'	System	24 Sep 2020 01:47:04

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T20:46:59', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '0e77fcc3-a8f5-4897-9894-ba8f740a78d2'	System	24 Sep 2020 01:47:04
User entered '23 Sep 2020 20:46'	System	24 Sep 2020 01:47:04



**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '23 Sep 2020 20:37'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	23 Sep 2020 22:17:40
User entered 'Day 2'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-24T23:43:24', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '8018c23e-4d9e-4257-9713-329d1d78fb75'	System	25 Sep 2020 04:43:55
User entered 'None (1)'	System	25 Sep 2020 04:43:55

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:18:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-24T23:43:27', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '8018c23e-4d9e-4257-9713-329d1d78fb75'	System	25 Sep 2020 04:43:55
User entered 'No (N)'	System	25 Sep 2020 04:43:55

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:18:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-24T23:43:36', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '8018c23e-4d9e-4257-9713-329d1d78fb75'	System	25 Sep 2020 04:43:55
User entered 'No (N)'	System	25 Sep 2020 04:43:55

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-24T23:43:49', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '8018c23e-4d9e-4257-9713-329d1d78fb75'	System	25 Sep 2020 04:43:55
User entered 'None (1)'	System	25 Sep 2020 04:43:55

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-24T23:43:51', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '8018c23e-4d9e-4257-9713-329d1d78fb75'	System	25 Sep 2020 04:43:55
User entered '24 Sep 2020 23:43'	System	25 Sep 2020 04:43:55



**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	23 Sep 2020 22:17:40
User entered 'Day 3'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T07:10:14', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'b3af398b-c70d-43fe-8c01-f30f72a1bf20'	System	26 Sep 2020 12:10:41
User entered 'None (1)'	System	26 Sep 2020 12:10:41

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:18:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T07:10:18', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'b3af398b-c70d-43fe-8c01-f30f72a1bf20'	System	26 Sep 2020 12:10:41
User entered 'No (N)'	System	26 Sep 2020 12:10:41

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:18:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T07:10:25', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'b3af398b-c70d-43fe-8c01-f30f72a1bf20'	System	26 Sep 2020 12:10:41
User entered 'No (N)'	System	26 Sep 2020 12:10:41

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T07:10:34', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'b3af398b-c70d-43fe-8c01-f30f72a1bf20'	System	26 Sep 2020 12:10:41
User entered 'None (1)'	System	26 Sep 2020 12:10:41

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T07:10:36', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'b3af398b-c70d-43fe-8c01-f30f72a1bf20'	System	26 Sep 2020 12:10:41
User entered '26 Sep 2020 07:10'	System	26 Sep 2020 12:10:41



**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	23 Sep 2020 22:17:40
User entered 'Day 4'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T23:12:04', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '9be8461d-e37c-40b9-8919-1eba06e95853'	System	27 Sep 2020 04:12:28
User entered 'None (1)'	System	27 Sep 2020 04:12:28

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:18:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T23:12:08', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '9be8461d-e37c-40b9-8919-1eba06e95853'	System	27 Sep 2020 04:12:28
User entered 'No (N)'	System	27 Sep 2020 04:12:28

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:18:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T23:12:12', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '9be8461d-e37c-40b9-8919-1eba06e95853'	System	27 Sep 2020 04:12:28
User entered 'No (N)'	System	27 Sep 2020 04:12:28

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T23:12:16', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '9be8461d-e37c-40b9-8919-1eba06e95853'	System	27 Sep 2020 04:12:28
User entered 'None (1)'	System	27 Sep 2020 04:12:28

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T23:12:24', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '9be8461d-e37c-40b9-8919-1eba06e95853'	System	27 Sep 2020 04:12:28
User entered '26 Sep 2020 23:12'	System	27 Sep 2020 04:12:28



**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	23 Sep 2020 22:17:40
User entered 'Day 5'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-27T23:22:17', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '4cc5616d-5563-406f-b264-80ca58cbd608'	System	28 Sep 2020 04:22:32
User entered 'None (1)'	System	28 Sep 2020 04:22:32

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:18:19

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-27T23:22:21', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '4cc5616d-5563-406f-b264-80ca58cbd608'	System	28 Sep 2020 04:22:32
User entered 'No (N)'	System	28 Sep 2020 04:22:32

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:18:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-27T23:22:23', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '4cc5616d-5563-406f-b264-80ca58cbd608'	System	28 Sep 2020 04:22:32
User entered 'No (N)'	System	28 Sep 2020 04:22:32

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-27T23:22:25', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '4cc5616d-5563-406f-b264-80ca58cbd608'	System	28 Sep 2020 04:22:32
User entered 'None (1)'	System	28 Sep 2020 04:22:32

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-27T23:22:29', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '4cc5616d-5563-406f-b264-80ca58cbd608'	System	28 Sep 2020 04:22:32
User entered '27 Sep 2020 23:22'	System	28 Sep 2020 04:22:32



**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:18:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	23 Sep 2020 22:17:40
User entered 'Day 6'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T05:40:49', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '0db64c92-b713-4d58-a8b1-8d66834b0309'	System	29 Sep 2020 10:41:21
User entered 'None (1)'	System	29 Sep 2020 10:41:21

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:18:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T05:40:52', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '0db64c92-b713-4d58-a8b1-8d66834b0309'	System	29 Sep 2020 10:41:21
User entered 'No (N)'	System	29 Sep 2020 10:41:21

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:18:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T05:40:56', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '0db64c92-b713-4d58-a8b1-8d66834b0309'	System	29 Sep 2020 10:41:21
User entered 'No (N)'	System	29 Sep 2020 10:41:21

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T05:41:00', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '0db64c92-b713-4d58-a8b1-8d66834b0309'	System	29 Sep 2020 10:41:21
User entered 'None (1)'	System	29 Sep 2020 10:41:21

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T05:41:17', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '0db64c92-b713-4d58-a8b1-8d66834b0309'	System	29 Sep 2020 10:41:21
User entered '29 Sep 2020 05:41'	System	29 Sep 2020 10:41:21



**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	23 Sep 2020 22:17:40
User entered 'Day 7'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T21:50:38', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'abaf7d8e-c04e-42e4-b6e1-9c40b4de61b8'	System	30 Sep 2020 02:51:03
User entered 'None (1)'	System	30 Sep 2020 02:51:03

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:18:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T21:50:41', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'abaf7d8e-c04e-42e4-b6e1-9c40b4de61b8'	System	30 Sep 2020 02:51:03
User entered 'No (N)'	System	30 Sep 2020 02:51:03

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:18:19

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T21:50:45', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'abaf7d8e-c04e-42e4-b6e1-9c40b4de61b8'	System	30 Sep 2020 02:51:03
User entered 'No (N)'	System	30 Sep 2020 02:51:03

US3272291

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T21:50:53', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'abaf7d8e-c04e-42e4-b6e1-9c40b4de61b8'	System	30 Sep 2020 02:51:03
User entered 'None (1)'	System	30 Sep 2020 02:51:03

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T21:50:56', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'abaf7d8e-c04e-42e4-b6e1-9c40b4de61b8'	System	30 Sep 2020 02:51:03
User entered '29 Sep 2020 21:50'	System	30 Sep 2020 02:51:03



**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	23 Sep 2020 22:17:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:18:19**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T17:28:00', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '3fd8acbe-134e-4097-85fb-af00791b09de'	System	23 Sep 2020 22:28:48
User entered 'None (0)'	System	23 Sep 2020 22:28:48

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T17:28:03', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '3fd8acbe-134e-4097-85fb-af00791b09de'	System	23 Sep 2020 22:28:48
User entered 'None (0)'	System	23 Sep 2020 22:28:48

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T17:28:11', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '3fd8acbe-134e-4097-85fb-af00791b09de'	System	23 Sep 2020 22:28:48
User entered 'None (0)'	System	23 Sep 2020 22:28:48

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T17:28:15', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '3fd8acbe-134e-4097-85fb-af00791b09de'	System	23 Sep 2020 22:28:48
User entered 'None (0)'	System	23 Sep 2020 22:28:48

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T17:28:18', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '3fd8acbe-134e-4097-85fb-af00791b09de'	System	23 Sep 2020 22:28:48
User entered 'None (0)'	System	23 Sep 2020 22:28:48



**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:18:19**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T17:28:23', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '3fd8acbe-134e-4097-85fb-af00791b09de'	System	23 Sep 2020 22:28:48
User entered 'None (0)'	System	23 Sep 2020 22:28:48

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T17:28:30', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '3fd8acbe-134e-4097-85fb-af00791b09de'	System	23 Sep 2020 22:28:48
User entered 'No (N)'	System	23 Sep 2020 22:28:48

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T17:28:45', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '3fd8acbe-134e-4097-85fb-af00791b09de'	System	23 Sep 2020 22:28:48
User entered '23 Sep 2020 17:28'	System	23 Sep 2020 22:28:48

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '23 Sep 2020 17:12'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '23 Sep 2020 19:42'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	23 Sep 2020 22:17:40
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:18:19**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T20:47:03', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '2b742d5d-3817-4516-a73e-a8761273cf95'	System	24 Sep 2020 01:49:20
User entered 'None (0)'	System	24 Sep 2020 01:49:20

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T20:47:04', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '2b742d5d-3817-4516-a73e-a8761273cf95'	System	24 Sep 2020 01:49:20
User entered 'None (0)'	System	24 Sep 2020 01:49:20



US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T20:47:07', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '2b742d5d-3817-4516-a73e-a8761273cf95'	System	24 Sep 2020 01:49:20
User entered 'None (0)'	System	24 Sep 2020 01:49:20

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T20:47:11', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '2b742d5d-3817-4516-a73e-a8761273cf95'	System	24 Sep 2020 01:49:20
User entered 'None (0)'	System	24 Sep 2020 01:49:20

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T20:47:13', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '2b742d5d-3817-4516-a73e-a8761273cf95'	System	24 Sep 2020 01:49:20
User entered 'None (0)'	System	24 Sep 2020 01:49:20

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:18:19**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T20:47:15', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '2b742d5d-3817-4516-a73e-a8761273cf95'	System	24 Sep 2020 01:49:20
User entered 'None (0)'	System	24 Sep 2020 01:49:20

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T20:49:12', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '2b742d5d-3817-4516-a73e-a8761273cf95'	System	24 Sep 2020 01:49:20
User entered 'No (N)'	System	24 Sep 2020 01:49:20

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-23T20:49:17', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '2b742d5d-3817-4516-a73e-a8761273cf95'	System	24 Sep 2020 01:49:20
User entered '23 Sep 2020 20:49'	System	24 Sep 2020 01:49:20

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '23 Sep 2020 20:37'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 22:17:40



**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	23 Sep 2020 22:17:40
User entered 'Day 2'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:18:19**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-24T23:43:56', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '2cda673a-ed87-479a-94de-4c9998307116'	System	25 Sep 2020 04:44:22
User entered 'None (0)'	System	25 Sep 2020 04:44:22

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:18:19**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-24T23:43:58', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '2cda673a-ed87-479a-94de-4c9998307116'	System	25 Sep 2020 04:44:22
User entered 'None (0)'	System	25 Sep 2020 04:44:22

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:18:19

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-24T23:44:00', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '2cda673a-ed87-479a-94de-4c9998307116'	System	25 Sep 2020 04:44:22
User entered 'None (0)'	System	25 Sep 2020 04:44:22

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:18:19

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-24T23:44:04', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '2cda673a-ed87-479a-94de-4c9998307116'	System	25 Sep 2020 04:44:22
User entered 'None (0)'	System	25 Sep 2020 04:44:22

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:18:19

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-24T23:44:06', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '2cda673a-ed87-479a-94de-4c9998307116'	System	25 Sep 2020 04:44:22
User entered 'None (0)'	System	25 Sep 2020 04:44:22

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:18:19**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-24T23:44:09', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '2cda673a-ed87-479a-94de-4c9998307116'	System	25 Sep 2020 04:44:22
User entered 'None (0)'	System	25 Sep 2020 04:44:22

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-24T23:44:12', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '2cda673a-ed87-479a-94de-4c9998307116'	System	25 Sep 2020 04:44:22
User entered 'No (N)'	System	25 Sep 2020 04:44:22



**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-24T23:44:17', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '2cda673a-ed87-479a-94de-4c9998307116'	System	25 Sep 2020 04:44:22
User entered '24 Sep 2020 23:44'	System	25 Sep 2020 04:44:22

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	23 Sep 2020 22:17:40
User entered 'Day 3'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:18:19**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T07:10:41', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'a3e9d081-c0fb-4d19-abcb-37f2e884827b'	System	26 Sep 2020 12:11:18
User entered 'None (0)'	System	26 Sep 2020 12:11:18

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:18:19**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T07:10:43', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'a3e9d081-c0fb-4d19-abcb-37f2e884827b'	System	26 Sep 2020 12:11:18
User entered 'None (0)'	System	26 Sep 2020 12:11:18

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:18:19

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T07:10:46', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'a3e9d081-c0fb-4d19-abcb-37f2e884827b'	System	26 Sep 2020 12:11:18
User entered 'None (0)'	System	26 Sep 2020 12:11:18

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:18:19

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T07:10:49', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'a3e9d081-c0fb-4d19-abcb-37f2e884827b'	System	26 Sep 2020 12:11:18
User entered 'None (0)'	System	26 Sep 2020 12:11:18



**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:18:19**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T07:10:56', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'a3e9d081-c0fb-4d19-abcb-37f2e884827b'	System	26 Sep 2020 12:11:18
User entered 'None (0)'	System	26 Sep 2020 12:11:18

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:18:19**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T07:11:00', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'a3e9d081-c0fb-4d19-abcb-37f2e884827b' User entered 'None (0)'	System	26 Sep 2020 12:11:18
	System	26 Sep 2020 12:11:18

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T07:11:09', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'a3e9d081-c0fb-4d19-abcb-37f2e884827b'	System	26 Sep 2020 12:11:18
User entered 'No (N)'	System	26 Sep 2020 12:11:18

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T07:11:11', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'a3e9d081-c0fb-4d19-abcb-37f2e884827b'	System	26 Sep 2020 12:11:18
User entered '26 Sep 2020 07:11'	System	26 Sep 2020 12:11:18

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	23 Sep 2020 22:17:40
User entered 'Day 4'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:18:19**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T23:12:29', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '986bf26f-91d5-44fc-9deb-16b68e00545f'	System	27 Sep 2020 04:15:48
User entered 'None (0)'	System	27 Sep 2020 04:15:48



**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:18:19**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T23:12:32', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '986bf26f-91d5-44fc-9deb-16b68e00545f'	System	27 Sep 2020 04:15:48
User entered 'None (0)'	System	27 Sep 2020 04:15:48

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:18:19

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T23:12:36', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '986bf26f-91d5-44fc-9deb-16b68e00545f'	System	27 Sep 2020 04:15:48
User entered 'None (0)'	System	27 Sep 2020 04:15:48

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:18:19**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T23:12:39', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '986bf26f-91d5-44fc-9deb-16b68e00545f'	System	27 Sep 2020 04:15:48
User entered 'None (0)'	System	27 Sep 2020 04:15:48

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:18:19**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T23:12:46', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '986bf26f-91d5-44fc-9deb-16b68e00545f'	System	27 Sep 2020 04:15:48
User entered 'None (0)'	System	27 Sep 2020 04:15:48

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:18:19**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T23:12:49', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '986bf26f-91d5-44fc-9deb-16b68e00545f'	System	27 Sep 2020 04:15:48
User entered 'None (0)'	System	27 Sep 2020 04:15:48

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T23:13:18', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '986bf26f-91d5-44fc-9deb-16b68e00545f'	System	27 Sep 2020 04:15:48
User entered 'No (N)'	System	27 Sep 2020 04:15:48

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-26T23:15:44', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '986bf26f-91d5-44fc-9deb-16b68e00545f'	System	27 Sep 2020 04:15:48
User entered '26 Sep 2020 23:15'	System	27 Sep 2020 04:15:48

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 22:17:40



**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 22:17:40

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:18:19

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	23 Sep 2020 22:17:40
User entered 'Day 5'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:18:19**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-27T23:22:34', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '695fc215-99c4-4b94-b86d-21197bac7db9'	System	28 Sep 2020 04:23:22
User entered 'None (0)'	System	28 Sep 2020 04:23:22

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:18:19**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-27T23:22:36', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '695fc215-99c4-4b94-b86d-21197bac7db9' User entered 'None (0)'	System	28 Sep 2020 04:23:22
	System	28 Sep 2020 04:23:22

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:18:19

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-27T23:22:44', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '695fc215-99c4-4b94-b86d-21197bac7db9' User entered 'None (0)'	System	28 Sep 2020 04:23:22
	System	28 Sep 2020 04:23:22

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:18:19

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-27T23:22:47', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '695fc215-99c4-4b94-b86d-21197bac7db9' User entered 'None (0)'	System	28 Sep 2020 04:23:22
	System	28 Sep 2020 04:23:22

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:18:19**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-27T23:22:59', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '695fc215-99c4-4b94-b86d-21197bac7db9'	System	28 Sep 2020 04:23:22
User entered 'None (0)'	System	28 Sep 2020 04:23:22

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:18:19**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-27T23:23:01', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '695fc215-99c4-4b94-b86d-21197bac7db9' User entered 'None (0)'	System	28 Sep 2020 04:23:22
	System	28 Sep 2020 04:23:22



US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-27T23:23:10', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '695fc215-99c4-4b94-b86d-21197bac7db9'	System	28 Sep 2020 04:23:22
User entered 'No (N)'	System	28 Sep 2020 04:23:22

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-27T23:23:18', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '695fc215-99c4-4b94-b86d-21197bac7db9' User entered '27 Sep 2020 23:23'	System	28 Sep 2020 04:23:22
	System	28 Sep 2020 04:23:22

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	23 Sep 2020 22:17:40
User entered 'Day 6'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:18:19**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T05:41:23', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'a5cbdb84-209a-4fbf-bfea-97122476f47d'	System	29 Sep 2020 10:42:00
User entered 'None (0)'	System	29 Sep 2020 10:42:00

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:18:19**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T05:41:25', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'a5cbdb84-209a-4fbf-bfea-97122476f47d'	System	29 Sep 2020 10:42:00
User entered 'None (0)'	System	29 Sep 2020 10:42:00

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:18:19

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T05:41:29', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'a5cbdb84-209a-4fbf-bfea-97122476f47d' User entered 'None (0)'	System	29 Sep 2020 10:42:00
	System	29 Sep 2020 10:42:00



US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:18:19

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T05:41:33', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'a5cbdb84-209a-4fbf-bfea-97122476f47d' User entered 'None (0)'	System	29 Sep 2020 10:42:00
	System	29 Sep 2020 10:42:00

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:18:19**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T05:41:36', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'a5cbdb84-209a-4fbf-bfea-97122476f47d'	System	29 Sep 2020 10:42:00
User entered 'None (0)'	System	29 Sep 2020 10:42:00

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:18:19**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T05:41:39', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'a5cbdb84-209a-4fbf-bfea-97122476f47d'	System	29 Sep 2020 10:42:00
User entered 'None (0)'	System	29 Sep 2020 10:42:00

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T05:41:45', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'a5cddb84-209a-4fbf-bfea-97122476f47d'	System	29 Sep 2020 10:42:00
User entered 'No (N)'	System	29 Sep 2020 10:42:00

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T05:41:57', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'a5cbdb84-209a-4fbf-bfea-97122476f47d'	System	29 Sep 2020 10:42:00
User entered '29 Sep 2020 05:41'	System	29 Sep 2020 10:42:00

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	23 Sep 2020 22:17:40
User entered 'Day 7'	System	23 Sep 2020 22:17:40



**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:18:19**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T21:51:07', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '9ad1168c-3687-4e13-a0cf-c88749c5b481'	System	30 Sep 2020 02:51:37
User entered 'None (0)'	System	30 Sep 2020 02:51:37

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:18:19

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T21:51:09', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '9ad1168c-3687-4e13-a0cf-c88749c5b481'	System	30 Sep 2020 02:51:37
User entered 'None (0)'	System	30 Sep 2020 02:51:37

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:18:19

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T21:51:11', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '9ad1168c-3687-4e13-a0cf-c88749c5b481'	System	30 Sep 2020 02:51:37
User entered 'None (0)'	System	30 Sep 2020 02:51:37

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:18:19

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T21:51:13', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '9ad1168c-3687-4e13-a0cf-c88749c5b481'	System	30 Sep 2020 02:51:37
User entered 'None (0)'	System	30 Sep 2020 02:51:37

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:18:19

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T21:51:15', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '9ad1168c-3687-4e13-a0cf-c88749c5b481'	System	30 Sep 2020 02:51:37
User entered 'None (0)'	System	30 Sep 2020 02:51:37

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:18:19**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T21:51:17', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '9ad1168c-3687-4e13-a0cf-c88749c5b481'	System	30 Sep 2020 02:51:37
User entered 'None (0)'	System	30 Sep 2020 02:51:37

US3272291

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T21:51:25', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '9ad1168c-3687-4e13-a0cf-c88749c5b481'	System	30 Sep 2020 02:51:37
User entered 'No (N)'	System	30 Sep 2020 02:51:37

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-09-29T21:51:32', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '9ad1168c-3687-4e13-a0cf-c88749c5b481'	System	30 Sep 2020 02:51:37
User entered '29 Sep 2020 21:51'	System	30 Sep 2020 02:51:37



**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:18:19**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 22:17:40

**US3272291**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:21:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 17:51:42

**US3272291**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:21:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '30 Sep 2020'	(b) (4), (b) (6)	02 Oct 2020 17:51:42

**US3272291**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:21:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Oct 2020 17:51:42

**US3272291**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:21:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 17:51:42

**US3272291**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:21:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 17:51:51

**US3272291**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:21:05
User entered 'I'	System	02 Oct 2020 17:51:51



**US3272291**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:46:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	Kayla Flege (b) (4)	07 Oct 2020 20:40:03

**US3272291**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:46:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '07 Oct 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	21 Nov 2020 23:48:25
User entered '7 Oct 2020'	Kayla Flege (b) (4)	07 Oct 2020 20:40:03

**US3272291**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:46:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Contact Made (CONTACT MADE)'	Kayla Flege (b) (4)	07 Oct 2020 20:40:03

**US3272291**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:46:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	Kayla Flege (b) (4)	07 Oct 2020 20:40:03

**US3272291**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:46:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	Kayla Flege (b) (4)	07 Oct 2020 20:40:06

**US3272291**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:46:06
User entered 'I'	System	07 Oct 2020 20:40:06

**US3272291**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:06:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 20:24:12

**US3272291**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:06:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 20:24:12



**US3272291**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:06:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Oct 2020 20:24:12

**US3272291**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:06:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 20:24:12

**US3272291**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:06:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 20:24:02

**US3272291**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:06:54
User entered 'I'	System	14 Oct 2020 20:24:02

**US3272291**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:55:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	Kayla Flege (b) (4)	21 Oct 2020 21:24:49

**US3272291**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:55:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '21 Oct 2020'	Kayla Flege (b) (4)	21 Oct 2020 21:24:49

**US3272291**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:55:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Clinic (Clinic)'	Kayla Flege (b) (4)	21 Oct 2020 21:24:49

**US3272291**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:55:29
User entered 'VISIT3'	System	21 Oct 2020 21:24:49



US3272291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:55:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	Kayla Flege (b) (4)	21 Oct 2020 21:25:23

**US3272291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:55:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '21 Oct 2020'	Kayla Flege (b) (4)	21 Oct 2020 21:25:23

**US3272291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:55:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '16:02'	Kayla Flege (b) (4)	21 Oct 2020 21:25:23

**US3272291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:55:29
User entered '21 Oct 2020 16:02'	System	21 Oct 2020 21:25:23

**US3272291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

**Temperature (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:55:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '36.6' C	Kayla Flege (b) (4)	21 Oct 2020 21:25:23

**US3272291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:55:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Oral (Oral)'	Kayla Flege (b) (4)	21 Oct 2020 21:25:23

**US3272291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:55:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	Kayla Flege (b) (4)	21 Oct 2020 21:25:23

**US3272291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:55:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '80'	Kayla Flege (b) (4)	21 Oct 2020 21:25:23



**US3272291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:55:29
User entered 'bpm'	System	21 Oct 2020 21:25:23

US3272291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:55:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '16'	Kayla Flege (b) (4)	21 Oct 2020 21:25:23

**US3272291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:55:29
User entered 'breaths/min'	System	21 Oct 2020 21:25:23

US3272291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:55:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '128'	Kayla Flege (b) (4)	21 Oct 2020 21:25:23

**US3272291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:55:29
User entered 'mmHg'	System	21 Oct 2020 21:25:23

US3272291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:55:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '82'	Kayla Flege (b) (4)	21 Oct 2020 21:25:23

US3272291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:55:29
User entered 'mmHg'	System	21 Oct 2020 21:25:23

**US3272291**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:55:29



US3272291

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:19

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:55:29

US3272291

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:18:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:55:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	Kayla Flege (b) (4)	21 Oct 2020 21:25:29

**US3272291**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:18:19**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:55:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '21 Oct 2020'	Kayla Flege (b) (4)	21 Oct 2020 21:25:29

**US3272291**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:18:19**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:55:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	Kayla Flege (b) (4)	21 Oct 2020 21:25:39

**US3272291**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:18:19**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:55:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '21 Oct 2020'	Kayla Flege (b) (4)	21 Oct 2020 21:25:39

US3272291

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:18:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:55:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '16:11'	Kayla Flege (b) (4)	21 Oct 2020 21:25:39

**US3272291**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:18:19**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:55:29
User entered '21 Oct 2020 16:11'	System	21 Oct 2020 21:25:39

US3272291

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:55:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	Kayla Flege (b) (4)	21 Oct 2020 21:25:44



**US3272291**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:55:29
User entered '1'	System	21 Oct 2020 21:25:44

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered 'Day 64'	System	22 Aug 2020 22:01:09

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-10-22T10:05:00', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '307cd93e-649f-47a2-9635-300d583ec8b1'	System	22 Oct 2020 15:05:39
User entered 'No (N)'	System	22 Oct 2020 15:05:39

US3272291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

Have you been exposed to someone with 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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-10-22T10:05:11', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '307cd93e-649f-47a2-9635-300d583ec8b1'	System	22 Oct 2020 15:05:39
User entered 'No (N)'	System	22 Oct 2020 15:05:39

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-10-22T10:05:32', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '307cd93e-649f-47a2-9635-300d583ec8b1' User entered '22 Oct 2020 10:05:32'	System	22 Oct 2020 15:05:39
	System	22 Oct 2020 15:05:39

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered '22 Oct 2020 00:01'	System	22 Aug 2020 22:01:09

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered '26 Oct 2020 23:59'	System	22 Aug 2020 22:01:09

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered 'Day 71'	System	22 Aug 2020 22:01:09



US3272291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

[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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-10-31T10:47:32', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'a3211394-b23a-49f0-abb1-64d2922597d1'	System	31 Oct 2020 15:47:55
User entered 'No (N)'	System	31 Oct 2020 15:47:55

US3272291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

Have you been exposed to someone with 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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-10-31T10:47:45', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'a3211394-b23a-49f0-abb1-64d2922597d1'	System	31 Oct 2020 15:47:55
User entered 'No (N)'	System	31 Oct 2020 15:47:55

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-10-31T10:47:49', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'a3211394-b23a-49f0-abb1-64d2922597d1' User entered '31 Oct 2020 10:47:49'	System	31 Oct 2020 15:47:55
	System	31 Oct 2020 15:47:55

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered '29 Oct 2020 00:01'	System	22 Aug 2020 22:01:09

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered '02 Nov 2020 23:59'	System	22 Aug 2020 22:01:09

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered 'Day 78'	System	22 Aug 2020 22:01:09

US3272291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-11-07T16:19:59', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'a4dabe80-56c1-432f-a902-17a11a9a4f85'	System	07 Nov 2020 22:20:09
User entered 'No (N)'	System	07 Nov 2020 22:20:09

US3272291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

Have you been exposed to someone with 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 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-11-07T16:20:02', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'a4dabe80-56c1-432f-a902-17a11a9a4f85'	System	07 Nov 2020 22:20:09
User entered 'No (N)'	System	07 Nov 2020 22:20:09



**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-11-07T16:20:05', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'a4dabe80-56c1-432f-a902-17a11a9a4f85'	System	07 Nov 2020 22:20:09
User entered '07 Nov 2020 16:20:05'	System	07 Nov 2020 22:20:09

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered '05 Nov 2020 00:01'	System	22 Aug 2020 22:01:09

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:36:33
Data entry locked.	System	22 Aug 2020 22:01:09
User entered '09 Nov 2020 23:59'	System	22 Aug 2020 22:01:09

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:14:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:25:34
Data entry locked.	System	22 Aug 2020 22:01:09
User entered 'Day 92'	System	22 Aug 2020 22:01:09

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:14:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:25:34

US3272291

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:18:19

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:14:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:14:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:14:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:14:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:14:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:14:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:14:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:14:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:14:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:14:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:14:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:14:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:14:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:14:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:14:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:14:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:14:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:14:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:14:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:14:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:14:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:14:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:14:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:14:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:14:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:25:34
Data entry locked.	System	22 Aug 2020 22:01:09
User entered '19 Nov 2020 00:01'	System	22 Aug 2020 22:01:09

**US3272291**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:14:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:25:34
Data entry locked.	System	22 Aug 2020 22:01:09
User entered '23 Nov 2020 23:59'	System	22 Aug 2020 22:01:09

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[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 (a35e300790ce3163)', Time: '2020-11-19T19:51:58', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '1798c8ed-583e-4341-9010-02d29ea7ed80'	System	20 Nov 2020 18:16:37
User entered 'No (N)'	System	20 Nov 2020 18:16:37

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Have you been exposed to someone with 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 (a35e300790ce3163)', Time: '2020-11-20T12:16:27', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '1798c8ed-583e-4341-9010-02d29ea7ed80'	System	20 Nov 2020 18:16:37
User entered 'No (N)'	System	20 Nov 2020 18:16:37

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-11-20T12:16:32', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '1798c8ed-583e-4341-9010-02d29ea7ed80'	System	20 Nov 2020 18:16:37
User entered '20 Nov 2020 12:16:32'	System	20 Nov 2020 18:16:37

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '16 Nov 2020 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '20 Nov 2020 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[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 (a35e300790ce3163)', Time: '2020-11-26T15:43:38', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '60cb5135-1f86-42cf-9d0b-ee29c261e7e9'	System	26 Nov 2020 21:45:20
User entered 'No (N)'	System	26 Nov 2020 21:45:20

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

Have you been exposed to someone with 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 (a35e300790ce3163)', Time: '2020-11-26T15:43:42', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '60cb5135-1f86-42cf-9d0b-ee29c261e7e9'	System	26 Nov 2020 21:45:20
User entered 'Yes (Y)'	System	26 Nov 2020 21:45:20



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

Please 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 (a35e300790ce3163)', Time: '2020-11-26T15:44:50', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '60cb5135-1f86-42cf-9d0b-ee29c261e7e9'	System	26 Nov 2020 21:45:20
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Nov 2020 21:45:20

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-11-26T15:45:09', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '60cb5135-1f86-42cf-9d0b-ee29c261e7e9'	System	26 Nov 2020 21:45:20
User entered '26 Nov 2020 15:45:09'	System	26 Nov 2020 21:45:20

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '23 Nov 2020 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '27 Nov 2020 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[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 (a35e300790ce3163)', Time: '2020-12-03T06:05:51', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '72e75dd8-b217-45a6-9a6d-d2deeb62181c'	System	03 Dec 2020 12:06:13
User entered 'No (N)'	System	03 Dec 2020 12:06:13

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

Have you been exposed to someone with 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 (a35e300790ce3163)', Time: '2020-12-03T06:06:03', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '72e75dd8-b217-45a6-9a6d-d2deeb62181c'	System	03 Dec 2020 12:06:13
User entered 'No (N)'	System	03 Dec 2020 12:06:13

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-12-03T06:06:07', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '72e75dd8-b217-45a6-9a6d-d2deeb62181c'	System	03 Dec 2020 12:06:13
User entered '03 Dec 2020 06:06:07'	System	03 Dec 2020 12:06:13



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '30 Nov 2020 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '04 Dec 2020 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[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 (a35e300790ce3163)', Time: '2020-12-07T02:43:58', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'c5535111-403d-4241-a820-0dffa6f57d8c'	System	07 Dec 2020 08:44:21
User entered 'No (N)'	System	07 Dec 2020 08:44:21

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Have you been exposed to someone with 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 (a35e300790ce3163)', Time: '2020-12-07T02:44:00', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'c5535111-403d-4241-a820-0dffa6f57d8c'	System	07 Dec 2020 08:44:21
User entered 'Yes (Y)'	System	07 Dec 2020 08:44:21

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

Please 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 (a35e300790ce3163)', Time: '2020-12-07T02:44:04', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'c5535111-403d-4241-a820-0dffa6f57d8c'	System	07 Dec 2020 08:44:21
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Dec 2020 08:44:21

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-12-07T02:44:10', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'c5535111-403d-4241-a820-0dffa6f57d8c'	System	07 Dec 2020 08:44:21
User entered '07 Dec 2020 02:44:10'	System	07 Dec 2020 08:44:21

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '07 Dec 2020 00:01'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '11 Dec 2020 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[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 (a35e300790ce3163)', Time: '2020-12-16T08:46:57', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'b5626c9b-836d-4bd8-bf6b-d085cad2a9fc'	System	16 Dec 2020 18:38:19
User entered 'No (N)'	System	16 Dec 2020 18:38:19

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

Have you been exposed to someone with 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 (a35e300790ce3163)', Time: '2020-12-16T12:38:05', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'b5626c9b-836d-4bd8-bf6b-d085cad2a9fc'	System	16 Dec 2020 18:38:19
User entered 'No (N)'	System	16 Dec 2020 18:38:19

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-12-16T12:38:14', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'b5626c9b-836d-4bd8-bf6b-d085cad2a9fc'	System	16 Dec 2020 18:38:19
User entered '16 Dec 2020 12:38:14'	System	16 Dec 2020 18:38:19

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '14 Dec 2020 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '18 Dec 2020 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '21 Dec 2020 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '25 Dec 2020 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[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 (a35e300790ce3163)', Time: '2020-12-30T21:53:46', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'e82e6dec-9ca1-4091-be12-ee1880ee9916'	System	31 Dec 2020 03:55:35
User entered 'No (N)'	System	31 Dec 2020 03:55:35

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Have you been exposed to someone with 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 (a35e300790ce3163)', Time: '2020-12-30T21:53:50', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'e82e6dec-9ca1-4091-be12-ee1880ee9916'	System	31 Dec 2020 03:55:35
User entered 'No (N)'	System	31 Dec 2020 03:55:35

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2020-12-30T21:55:32', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'e82e6dec-9ca1-4091-be12-ee1880ee9916'	System	31 Dec 2020 03:55:35
User entered '30 Dec 2020 21:55:32'	System	31 Dec 2020 03:55:35

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '28 Dec 2020 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '01 Jan 2021 23:59'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[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 (a35e300790ce3163)', Time: '2021-01-04T12:04:59', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '2ff1bc23-1557-43aa-80e0-3183b6cbc431'	System	04 Jan 2021 18:05:29
User entered 'No (N)'	System	04 Jan 2021 18:05:29

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

Have you been exposed to someone with 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 (a35e300790ce3163)', Time: '2021-01-04T12:05:03', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '2ff1bc23-1557-43aa-80e0-3183b6cbc431'	System	04 Jan 2021 18:05:29
User entered 'No (N)'	System	04 Jan 2021 18:05:29

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2021-01-04T12:05:26', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '2ff1bc23-1557-43aa-80e0-3183b6cbc431'	System	04 Jan 2021 18:05:29
User entered '04 Jan 2021 12:05:26'	System	04 Jan 2021 18:05:29

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '04 Jan 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '08 Jan 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[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 (a35e300790ce3163)', Time: '2021-01-12T18:34:27', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '3bbd19d9-7727-4d57-9fe3-fff3dfa4a8ab'	System	13 Jan 2021 00:35:48
User entered 'No (N)'	System	13 Jan 2021 00:35:48



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Have you been exposed to someone with 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 (a35e300790ce3163)', Time: '2021-01-12T18:34:31', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '3bbd19d9-7727-4d57-9fe3-fff3dfa4a8ab'	System	13 Jan 2021 00:35:48
User entered 'No (N)'	System	13 Jan 2021 00:35:48

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2021-01-12T18:35:45', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '3bbd19d9-7727-4d57-9fe3-fff3dfa4a8ab' User entered '12 Jan 2021 18:35:45'	System	13 Jan 2021 00:35:48
	System	13 Jan 2021 00:35:48

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '11 Jan 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '15 Jan 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[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 (a35e300790ce3163)', Time: '2021-01-18T05:40:29', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '7a0eef66-a9a9-48d3-8525-0ff6bc573364'	System	18 Jan 2021 11:44:22
User entered 'Yes (Y)'	System	18 Jan 2021 11:44:22

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Have you been exposed to someone with 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 (a35e300790ce3163)', Time: '2021-01-18T05:40:42', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '7a0eef66-a9a9-48d3-8525-0ff6bc573364'	System	18 Jan 2021 11:44:22
User entered 'No (N)'	System	18 Jan 2021 11:44:22

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[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 (a35e300790ce3163)', Time: '2021-01-18T05:41:05', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '7a0eef66-a9a9-48d3-8525-0ff6bc573364'	System	18 Jan 2021 11:44:22
User entered 'Yes (Y)'	System	18 Jan 2021 11:44:22



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2021-01-18T05:42:03', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '7a0eef66-a9a9-48d3-8525-0ff6bc573364'	System	18 Jan 2021 11:44:22
User entered '0'	System	18 Jan 2021 11:44:22

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2021-01-18T05:42:03', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '7a0eef66-a9a9-48d3-8525-0ff6bc573364'	System	18 Jan 2021 11:44:22
User entered '0'	System	18 Jan 2021 11:44:22

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2021-01-18T05:42:03', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '7a0eef66-a9a9-48d3-8525-0ff6bc573364'	System	18 Jan 2021 11:44:22
User entered '0'	System	18 Jan 2021 11:44:22

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2021-01-18T05:42:03', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '7a0eef66-a9a9-48d3-8525-0ff6bc573364'	System	18 Jan 2021 11:44:22
User entered '0'	System	18 Jan 2021 11:44:22

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2021-01-18T05:42:03', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '7a0eef66-a9a9-48d3-8525-0ff6bc573364'	System	18 Jan 2021 11:44:22
User entered '0'	System	18 Jan 2021 11:44:22

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2021-01-18T05:42:03', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '7a0eef66-a9a9-48d3-8525-0ff6bc573364'	System	18 Jan 2021 11:44:22
User entered '1'	System	18 Jan 2021 11:44:22

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2021-01-18T05:42:03', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '7a0eef66-a9a9-48d3-8525-0ff6bc573364'	System	18 Jan 2021 11:44:22
User entered '1'	System	18 Jan 2021 11:44:22

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2021-01-18T05:42:03', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '7a0eef66-a9a9-48d3-8525-0ff6bc573364'	System	18 Jan 2021 11:44:22
User entered '1'	System	18 Jan 2021 11:44:22



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2021-01-18T05:42:03', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '7a0eef66-a9a9-48d3-8525-0ff6bc573364'	System	18 Jan 2021 11:44:22
User entered '0'	System	18 Jan 2021 11:44:22

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2021-01-18T05:42:03', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '7a0eef66-a9a9-48d3-8525-0ff6bc573364'	System	18 Jan 2021 11:44:22
User entered '0'	System	18 Jan 2021 11:44:22

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2021-01-18T05:42:03', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '7a0eef66-a9a9-48d3-8525-0ff6bc573364'	System	18 Jan 2021 11:44:22
User entered '0'	System	18 Jan 2021 11:44:22

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2021-01-18T05:42:03', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '7a0eef66-a9a9-48d3-8525-0ff6bc573364'	System	18 Jan 2021 11:44:22
User entered '0'	System	18 Jan 2021 11:44:22

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2021-01-18T05:42:03', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '7a0eef66-a9a9-48d3-8525-0ff6bc573364'	System	18 Jan 2021 11:44:22
User entered '1'	System	18 Jan 2021 11:44:22

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2021-01-18T05:42:03', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '7a0eef66-a9a9-48d3-8525-0ff6bc573364' User entered '0'	System	18 Jan 2021 11:44:22

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2021-01-18T05:42:03', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '7a0eef66-a9a9-48d3-8525-0ff6bc573364'	System	18 Jan 2021 11:44:22
User entered '0'	System	18 Jan 2021 11:44:22

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2021-01-18T05:42:03', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '7a0eef66-a9a9-48d3-8525-0ff6bc573364'	System	18 Jan 2021 11:44:22
User entered '0'	System	18 Jan 2021 11:44:22



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2021-01-18T05:42:03', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '7a0eef66-a9a9-48d3-8525-0ff6bc573364'	System	18 Jan 2021 11:44:22
User entered '0'	System	18 Jan 2021 11:44:22

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

Please 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 (a35e300790ce3163)', Time: '2021-01-18T05:42:17', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '7a0eef66-a9a9-48d3-8525-0ff6bc573364'	System	18 Jan 2021 11:44:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Jan 2021 11:44:22

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[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 (a35e300790ce3163)', Time: '2021-01-18T05:42:51', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '7a0eef66-a9a9-48d3-8525-0ff6bc573364'	System	18 Jan 2021 11:44:22
User entered 'Yes (Y)'	System	18 Jan 2021 11:44:22

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

Please 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 (a35e300790ce3163)', Time: '2021-01-18T05:43:41', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '7a0eef66-a9a9-48d3-8525-0ff6bc573364'	System	18 Jan 2021 11:44:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Jan 2021 11:44:22

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2021-01-18T05:44:08', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '7a0eef66-a9a9-48d3-8525-0ff6bc573364'	System	18 Jan 2021 11:44:22
User entered '18 Jan 2021 05:44:08'	System	18 Jan 2021 11:44:22

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '18 Jan 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '22 Jan 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[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 (a35e300790ce3163)', Time: '2021-01-25T14:18:49', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'fc378349-7b9f-4a62-9582-4e84720ea09d'	System	25 Jan 2021 20:19:00
User entered 'No (N)'	System	25 Jan 2021 20:19:00

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

Have you been exposed to someone with 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 (a35e300790ce3163)', Time: '2021-01-25T14:18:53', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'fc378349-7b9f-4a62-9582-4e84720ea09d'	System	25 Jan 2021 20:19:00
User entered 'No (N)'	System	25 Jan 2021 20:19:00

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2021-01-25T14:18:56', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'fc378349-7b9f-4a62-9582-4e84720ea09d'	System	25 Jan 2021 20:19:00
User entered '25 Jan 2021 14:18:56'	System	25 Jan 2021 20:19:00

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '25 Jan 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '29 Jan 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[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 (a35e300790ce3163)', Time: '2021-02-01T20:23:11', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '65fca3b0-b3bf-40d1-8c6d-d591b9800376'	System	02 Feb 2021 02:23:27
User entered 'No (N)'	System	02 Feb 2021 02:23:27

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

Have you been exposed to someone with 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 (a35e300790ce3163)', Time: '2021-02-01T20:23:13', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '65fca3b0-b3bf-40d1-8c6d-d591b9800376'	System	02 Feb 2021 02:23:27
User entered 'No (N)'	System	02 Feb 2021 02:23:27



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2021-02-01T20:23:24', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '65fca3b0-b3bf-40d1-8c6d-d591b9800376'	System	02 Feb 2021 02:23:27
User entered '01 Feb 2021 20:23:24'	System	02 Feb 2021 02:23:27

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '01 Feb 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '05 Feb 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[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 (a35e300790ce3163)', Time: '2021-02-08T20:04:10', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'be311f38-d37a-4eb9-9d69-6ff958c508e6'	System	09 Feb 2021 02:11:45
User entered 'No (N)'	System	09 Feb 2021 02:11:45

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

Have you been exposed to someone with 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 (a35e300790ce3163)', Time: '2021-02-08T20:04:15', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'be311f38-d37a-4eb9-9d69-6ff958c508e6'	System	09 Feb 2021 02:11:45
User entered 'No (N)'	System	09 Feb 2021 02:11:45

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2021-02-08T20:04:21', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'be311f38-d37a-4eb9-9d69-6ff958c508e6'	System	09 Feb 2021 02:11:45
User entered '08 Feb 2021 20:04:21'	System	09 Feb 2021 02:11:45

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '08 Feb 2021 00:01'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '12 Feb 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[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 (a35e300790ce3163)', Time: '2021-02-15T05:08:20', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'eb1c183c-2ee2-4f57-996d-acef9cea7e19'	System	15 Feb 2021 11:08:42
User entered 'No (N)'	System	15 Feb 2021 11:08:42

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

Have you been exposed to someone with 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 (a35e300790ce3163)', Time: '2021-02-15T05:08:36', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'eb1c183c-2ee2-4f57-996d-acef9cea7e19'	System	15 Feb 2021 11:08:42
User entered 'No (N)'	System	15 Feb 2021 11:08:42

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2021-02-15T05:08:39', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'eb1c183c-2ee2-4f57-996d-acef9cea7e19'	System	15 Feb 2021 11:08:42
User entered '15 Feb 2021 05:08:39'	System	15 Feb 2021 11:08:42

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '15 Feb 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '19 Feb 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[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 (a35e300790ce3163)', Time: '2021-02-22T10:15:56', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '14760c7f-a52d-4037-bb3a-cfa9e7e0485f'	System	22 Feb 2021 16:16:07
User entered 'No (N)'	System	22 Feb 2021 16:16:07

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

Have you been exposed to someone with 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 (a35e300790ce3163)', Time: '2021-02-22T10:15:58', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '14760c7f-a52d-4037-bb3a-cfa9e7e0485f'	System	22 Feb 2021 16:16:07
User entered 'No (N)'	System	22 Feb 2021 16:16:07

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2021-02-22T10:16:03', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '14760c7f-a52d-4037-bb3a-cfa9e7e0485f' User entered '22 Feb 2021 10:16:03'	System	22 Feb 2021 16:16:07
	System	22 Feb 2021 16:16:07

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '22 Feb 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '26 Feb 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[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 (a35e300790ce3163)', Time: '2021-03-01T21:03:11', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'c3022923-3b12-4cd6-9995-dce64ea61ecf'	System	02 Mar 2021 03:07:04
User entered 'No (N)'	System	02 Mar 2021 03:07:04

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Have you been exposed to someone with 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 (a35e300790ce3163)', Time: '2021-03-01T21:03:15', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'c3022923-3b12-4cd6-9995-dce64ea61ecf'	System	02 Mar 2021 03:07:04
User entered 'No (N)'	System	02 Mar 2021 03:07:04



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2021-03-01T21:03:19', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'c3022923-3b12-4cd6-9995-dce64ea61ecf'	System	02 Mar 2021 03:07:04
User entered '01 Mar 2021 21:03:19'	System	02 Mar 2021 03:07:04

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '01 Mar 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '05 Mar 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[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 (a35e300790ce3163)', Time: '2021-03-10T19:00:10', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '100d1576-9dc2-4e26-82a5-add0b1c34fa5'	System	11 Mar 2021 01:00:51
User entered 'No (N)'	System	11 Mar 2021 01:00:51

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

Have you been exposed to someone with 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 (a35e300790ce3163)', Time: '2021-03-10T19:00:16', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '100d1576-9dc2-4e26-82a5-add0b1c34fa5'	System	11 Mar 2021 01:00:51
User entered 'No (N)'	System	11 Mar 2021 01:00:51

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2021-03-10T19:00:32', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '100d1576-9dc2-4e26-82a5-add0b1c34fa5'	System	11 Mar 2021 01:00:51
User entered '10 Mar 2021 19:00:32'	System	11 Mar 2021 01:00:51

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '08 Mar 2021 00:01'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '12 Mar 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[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 (8366537772fa2f31)', Time: '2021-03-15T00:01:19-05:00', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '28a04191-d882-4d00-831d-716a9de7bc4f'	System	15 Mar 2021 05:01:44
User entered 'No (N)'	System	15 Mar 2021 05:01:44

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

Have you been exposed to someone with 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 (8366537772fa2f31)', Time: '2021-03-15T00:01:22-05:00', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '28a04191-d882-4d00-831d-716a9de7bc4f'	System	15 Mar 2021 05:01:44
User entered 'No (N)'	System	15 Mar 2021 05:01:44

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8366537772fa2f31)', Time: '2021-03-15T00:01:43-05:00', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '28a04191-d882-4d00-831d-716a9de7bc4f' User entered '15 Mar 2021 00:01:43'	System	15 Mar 2021 05:01:44

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '15 Mar 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '19 Mar 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[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 (8366537772fa2f31)', Time: '2021-03-23T17:25:47-05:00', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '3600124f-be96-416d-8adb-6a6fd468d85b'	System	23 Mar 2021 22:25:57
User entered 'No (N)'	System	23 Mar 2021 22:25:57

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

Have you been exposed to someone with 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 (8366537772fa2f31)', Time: '2021-03-23T17:25:51-05:00', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '3600124f-be96-416d-8adb-6a6fd468d85b'	System	23 Mar 2021 22:25:57
User entered 'No (N)'	System	23 Mar 2021 22:25:57

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8366537772fa2f31)', Time: '2021-03-23T17:25:54-05:00', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '3600124f-be96-416d-8adb-6a6fd468d85b' User entered '23 Mar 2021 17:25:54'	System	23 Mar 2021 22:25:57
	System	23 Mar 2021 22:25:57

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '22 Mar 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '26 Mar 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[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 (8366537772fa2f31)', Time: '2021-03-29T05:22:11-05:00', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '51159cbf-ddf4-4ef1-a794-0eaf9c0c35cb' User entered 'No (N)'	System	29 Mar 2021 10:22:22

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

Have you been exposed to someone with 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 (8366537772fa2f31)', Time: '2021-03-29T05:22:15-05:00', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '51159cbf-ddf4-4ef1-a794-0eaf9c0c35cb' User entered 'No (N)'	System	29 Mar 2021 10:22:22



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8366537772fa2f31)', Time: '2021-03-29T05:22:19-05:00', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '51159cbf-ddf4-4ef1-a794-0eaf9c0c35cb' User entered '29 Mar 2021 05:22:19'	System	29 Mar 2021 10:22:22

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '29 Mar 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '02 Apr 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[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 (8366537772fa2f31)', Time: '2021-04-05T05:40:35-05:00', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'e6875e3e-ae71-4f4f-9971-bb525328fd48'	System	05 Apr 2021 10:40:55
User entered 'No (N)'	System	05 Apr 2021 10:40:55

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

Have you been exposed to someone with 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 (8366537772fa2f31)', Time: '2021-04-05T05:40:48-05:00', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'e6875e3e-ae71-4f4f-9971-bb525328fd48'	System	05 Apr 2021 10:40:55
User entered 'No (N)'	System	05 Apr 2021 10:40:55

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8366537772fa2f31)', Time: '2021-04-05T05:40:53-05:00', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'e6875e3e-ae71-4f4f-9971-bb525328fd48'	System	05 Apr 2021 10:40:55
User entered '05 Apr 2021 05:40:53'	System	05 Apr 2021 10:40:55

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '05 Apr 2021 00:01'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '09 Apr 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[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 (8366537772fa2f31)', Time: '2021-04-12T07:48:18-05:00', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'bb150838-96f9-489c-bd8c-74f013c60f3a' User entered 'No (N)'	System	12 Apr 2021 12:48:30
	System	12 Apr 2021 12:48:30

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

Have you been exposed to someone with 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 (8366537772fa2f31)', Time: '2021-04-12T07:48:23-05:00', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'bb150838-96f9-489c-bd8c-74f013c60f3a'	System	12 Apr 2021 12:48:30
User entered 'No (N)'	System	12 Apr 2021 12:48:30

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8366537772fa2f31)', Time: '2021-04-12T07:48:26-05:00', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'bb150838-96f9-489c-bd8c-74f013c60f3a' User entered '12 Apr 2021 07:48:26'	System	12 Apr 2021 12:48:30
	System	12 Apr 2021 12:48:30

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '12 Apr 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '16 Apr 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[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 (8366537772fa2f31)', Time: '2021-04-19T05:37:21-05:00', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '62645bc5-69c1-42db-9879-a451db948dfb' User entered 'No (N)'	System	19 Apr 2021 10:37:35
	System	19 Apr 2021 10:37:35

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

Have you been exposed to someone with 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 (8366537772fa2f31)', Time: '2021-04-19T05:37:26-05:00', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '62645bc5-69c1-42db-9879-a451db948dfb'	System	19 Apr 2021 10:37:35
User entered 'No (N)'	System	19 Apr 2021 10:37:35

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8366537772fa2f31)', Time: '2021-04-19T05:37:30-05:00', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '62645bc5-69c1-42db-9879-a451db948dfb' User entered '19 Apr 2021 05:37:30'	System	19 Apr 2021 10:37:35
	System	19 Apr 2021 10:37:35

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '19 Apr 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '23 Apr 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[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 (8366537772fa2f31)', Time: '2021-04-26T00:01:20-05:00', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'bd41a18c-9837-4fc5-b0f0-0eb40c421545' User entered 'No (N)'	System	26 Apr 2021 05:01:31
	System	26 Apr 2021 05:01:31

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

Have you been exposed to someone with 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 (8366537772fa2f31)', Time: '2021-04-26T00:01:22-05:00', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'bd41a18c-9837-4fc5-b0f0-0eb40c421545'	System	26 Apr 2021 05:01:31
User entered 'No (N)'	System	26 Apr 2021 05:01:31



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8366537772fa2f31)', Time: '2021-04-26T00:01:28-05:00', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: 'bd41a18c-9837-4fc5-b0f0-0eb40c421545'	System	26 Apr 2021 05:01:31
User entered '26 Apr 2021 00:01:28'	System	26 Apr 2021 05:01:31

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '26 Apr 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '30 Apr 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '03 May 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '07 May 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '10 May 2021 00:01'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '14 May 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '17 May 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '21 May 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '24 May 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '28 May 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '31 May 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '04 Jun 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '07 Jun 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '11 Jun 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '14 Jun 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '18 Jun 2021 23:59'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '21 Jun 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '25 Jun 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '28 Jun 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '02 Jul 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '05 Jul 2021 00:01'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '09 Jul 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '12 Jul 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '16 Jul 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '19 Jul 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '23 Jul 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '26 Jul 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '30 Jul 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '02 Aug 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '06 Aug 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '09 Aug 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '13 Aug 2021 23:59'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '16 Aug 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '20 Aug 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '23 Aug 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '27 Aug 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '30 Aug 2021 00:01'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '03 Sep 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '06 Sep 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '10 Sep 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '13 Sep 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '17 Sep 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '20 Sep 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '24 Sep 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '27 Sep 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '01 Oct 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '04 Oct 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '08 Oct 2021 23:59'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '11 Oct 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '15 Oct 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '18 Oct 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '22 Oct 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '25 Oct 2021 00:01'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '29 Oct 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '01 Nov 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '05 Nov 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '08 Nov 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '12 Nov 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '15 Nov 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '19 Nov 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '22 Nov 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '26 Nov 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '29 Nov 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '03 Dec 2021 23:59'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '06 Dec 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '10 Dec 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '13 Dec 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '17 Dec 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '20 Dec 2021 00:01'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '24 Dec 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '27 Dec 2021 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '31 Dec 2021 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '03 Jan 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '07 Jan 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '10 Jan 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '14 Jan 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '17 Jan 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '21 Jan 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '24 Jan 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '28 Jan 2022 23:59'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '31 Jan 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '04 Feb 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '07 Feb 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '11 Feb 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '14 Feb 2022 00:01'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '18 Feb 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '21 Feb 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '25 Feb 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '28 Feb 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '04 Mar 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '07 Mar 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '11 Mar 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '14 Mar 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '18 Mar 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '21 Mar 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '25 Mar 2022 23:59'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '28 Mar 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '01 Apr 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '04 Apr 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '08 Apr 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '11 Apr 2022 00:01'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '15 Apr 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '18 Apr 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '22 Apr 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '25 Apr 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '29 Apr 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '02 May 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '06 May 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '09 May 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '13 May 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '16 May 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '20 May 2022 23:59'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '23 May 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '27 May 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '30 May 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '03 Jun 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '06 Jun 2022 00:01'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '10 Jun 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '13 Jun 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '17 Jun 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '20 Jun 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '24 Jun 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '27 Jun 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '01 Jul 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '04 Jul 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '08 Jul 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '11 Jul 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '15 Jul 2022 23:59'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '18 Jul 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '22 Jul 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '25 Jul 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '29 Jul 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '01 Aug 2022 00:01'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '05 Aug 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '08 Aug 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '12 Aug 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '15 Aug 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '19 Aug 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '22 Aug 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '26 Aug 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '29 Aug 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '02 Sep 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '05 Sep 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '09 Sep 2022 23:59'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '12 Sep 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '16 Sep 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '19 Sep 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '23 Sep 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '26 Sep 2022 00:01'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '30 Sep 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '03 Oct 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '07 Oct 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '10 Oct 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '14 Oct 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:25:34



**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '17 Oct 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '21 Oct 2022 23:59'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '24 Oct 2022 00:01'	System	20 Nov 2020 01:25:34

**US3272291**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:18:19**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:25:34
Amendment Manager: User entered '28 Oct 2022 23:59'	System	20 Nov 2020 01:25:34

US3272291

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:18:19**

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)	25 Apr 2021 09:14:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2021-03-05T18:12:47', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '55a0ccab-6a07-4805-8e90-cecf9970824b'	System	06 Mar 2021 00:15:53
User entered 'No (N)'	System	06 Mar 2021 00:15:53

**US3272291**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:14:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a35e300790ce3163)', Time: '2021-03-05T18:12:50', User OID: 'PatientReportedOutcome (US3272291)', ODM File OID: '55a0ccab-6a07-4805-8e90-cecf9970824b'	System	06 Mar 2021 00:15:53
User entered '05 Mar 2021 18:12:50'	System	06 Mar 2021 00:15:53

**US3272291**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 23:11:01



**US3272291**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '19 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 23:11:01

**US3272291**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Nov 2020 23:11:01

**US3272291**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 23:11:01

**US3272291**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 23:11:13

**US3272291**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:36:27
User entered 'I'	System	19 Nov 2020 23:11:13

**US3272291**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	Kayla Flege (b) (4)	21 Dec 2020 22:35:01
	(b) (4)	

**US3272291**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '21 Dec 2020'	Kayla Flege (b) (4)	21 Dec 2020 22:35:01
	(b) (4)	

**US3272291**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Contact Made (CONTACT MADE)'	Kayla Flege (b) (4)	21 Dec 2020 22:35:01
	(b) (4)	



**US3272291**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	Kayla Flege (b) (4)	21 Dec 2020 22:35:01
	(b) (4)	

US3272291

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	Kayla Flege (b) (4)	21 Dec 2020 22:35:07
	(b) (4)	

**US3272291**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:51:29
User entered 'I'	System	21 Dec 2020 22:35:07

**US3272291**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 14:18:05

**US3272291**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '21 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 14:18:05

**US3272291**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Jan 2021 14:18:05

**US3272291**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 14:18:05

US3272291

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 14:18:10



**US3272291**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:28:25
User entered 'I'	System	22 Jan 2021 14:18:10

**US3272291**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:24:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 20:22:56

**US3272291**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:24:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '22 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 20:22:56

**US3272291**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:24:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Feb 2021 20:22:56

**US3272291**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:24:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 20:22:56

**US3272291**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:24:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 20:23:00

**US3272291**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:24:20
User entered 'I'	System	23 Feb 2021 20:23:00

**US3272291**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:58:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	Ashley Bell (b) (4)	17 Mar 2021 02:36:14



**US3272291**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:58:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '13 Mar 2021'	Ashley Bell (b) (4)	17 Mar 2021 02:36:14

US3272291

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:18:19

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:58:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Clinic (Clinic)'	Ashley Bell (b) (4)	17 Mar 2021 02:36:14

**US3272291**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:58:36
User entered 'VISIT4'	System	17 Mar 2021 02:36:14

US3272291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:58:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'No (N)'	Ashley Bell (b) (4)	30 Mar 2021 18:02:42

**US3272291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:58:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 18:02:42

**US3272291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:58:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 18:02:42

**US3272291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:58:36
User entered empty.	System	30 Mar 2021 18:02:42

US3272291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:58:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 18:02:42



**US3272291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:58:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 18:02:42

**US3272291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:58:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 18:02:42

**US3272291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:58:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 18:02:42

**US3272291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:58:36
User entered empty.	System	30 Mar 2021 18:02:42

US3272291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:58:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 18:02:42

**US3272291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:58:36
User entered empty.	System	30 Mar 2021 18:02:42

US3272291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:58:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 18:02:42

**US3272291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:58:36
User entered empty.	System	30 Mar 2021 18:02:42



US3272291

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:58:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 18:02:42

**US3272291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:58:36
User entered empty.	System	30 Mar 2021 18:02:42

**US3272291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:58:36

**US3272291**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:58:36

**US3272291**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:18:19**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:58:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	Ashley Bell (b) (4)	17 Mar 2021 02:36:22

**US3272291**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:18:19**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:58:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '13 Mar 2021'	Ashley Bell (b) (4)	17 Mar 2021 02:36:22

**US3272291**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:18:19**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:58:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	Ashley Bell (b) (4)	17 Mar 2021 02:36:35

**US3272291**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:18:19**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:58:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '13 Mar 2021'	Ashley Bell (b) (4)	17 Mar 2021 02:36:35



**US3272291**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:18:19**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:58:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '11:08'	Ashley Bell (b) (4)	17 Mar 2021 02:36:35

**US3272291**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:18:19**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:58:36
User entered '13 Mar 2021 11:08'	System	17 Mar 2021 02:36:35

US3272291

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:58:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	Ashley Bell (b) (4)	17 Mar 2021 02:36:39

**US3272291**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:58:36
User entered '1'	System	17 Mar 2021 02:36:39

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:18:19**

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:42:54
User entered '10 Dec 2020'	Kayla Flege (b) (4) (b) (4)	10 Dec 2020 23:58:55

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:18:19**

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:42:54
User entered '13:00'	Kayla Flege (b) (4)	10 Dec 2020 23:58:55
	(b) (4)	

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:18:19**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:51
User entered '10 Dec 2020 13:00'	System	10 Dec 2020 23:58:55

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:18:19**

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:42:54
User entered 'Convalescent Tele-visit (Convalescent Tele-visit)'	Kayla Flege (b) (4) (b) (4)	10 Dec 2020 23:58:55



**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:18:19**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:18:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:42:54
User entered 'Yes (Y)'	Kayla Flege (b) (4)	10 Dec 2020 23:58:55
	(b) (4)	

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
User entered 'Day 1 (Day 1)'	Kayla Flege (b) (4)	10 Dec 2020 23:59:50

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '10 Dec 2020'	Kayla Flege (b) (4)	10 Dec 2020 23:59:50
	(b) (4)	

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '0'	Kayla Flege (b) (4)	10 Dec 2020 23:59:50
	(b) (4)	

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '99'	Kayla Flege (b) (4)	10 Dec 2020 23:59:50
	(b) (4)	

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User entered '%'	System	10 Dec 2020 23:59:50

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '36.5' C	Kayla Flege (b) (4) (b) (4)	10 Dec 2020 23:59:50

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	10 Dec 2020 23:59:50



**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'Mild (Mild)'	Kayla Flege (b) (4) (b) (4)	10 Dec 2020 23:59:50

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	10 Dec 2020 23:59:50

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	10 Dec 2020 23:59:50

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'Mild (Mild)'	Kayla Flege (b) (4) (b) (4)	10 Dec 2020 23:59:50

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	10 Dec 2020 23:59:50

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	10 Dec 2020 23:59:50

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	10 Dec 2020 23:59:50

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:18:19**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	10 Dec 2020 23:59:50



**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:18:19**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	10 Dec 2020 23:59:50

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'Mild (Mild)'	Kayla Flege (b) (4) (b) (4)	10 Dec 2020 23:59:50

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	10 Dec 2020 23:59:50

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	10 Dec 2020 23:59:50

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	10 Dec 2020 23:59:50

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:18:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	10 Dec 2020 23:59:50

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'Mild (Mild)'	Kayla Flege (b) (4) (b) (4)	10 Dec 2020 23:59:50

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
User entered 'Day 2 (Day 2)'	Andrea Clement (b) (4)	12 Dec 2020 22:47:24



US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '11 Dec 2020'	Andrea Clement (b) (4)	12 Dec 2020 22:47:24

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '0'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '99'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User entered '%'	System	12 Dec 2020 22:47:24

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '98.3' F	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24



US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'Moderate (Moderate)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:18:19**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:18:19**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24



US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:18:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
User entered 'Day 3 (Day 3)'	Andrea Clement (b) (4)	12 Dec 2020 22:47:24

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:18:19**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '12 Dec 2020'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '0'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24



US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '98'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User entered '%'	System	12 Dec 2020 22:47:24

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '97.0' F	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24



US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:18:19**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Andrea Clement (b) (4)	12 Dec 2020 22:47:24

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:18:19**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:19

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:18:19**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24



US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:18:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:18:19**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:24

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
User closed query 'per CDM: there is already a day 3 present on the day prior to this, please clarify symptom day(s)' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 09:43:52
Query 'per CDM: there is already a day 3 present on the day prior to this, please clarify symptom day(s)' answered with 'updated' (Site from DM).		19 Mar 2021 22:49:13
User entered 'Day 4 (Day 4)' reason for change:		19 Mar 2021 22:49:02
Data Entry Error		
User opened query 'per CDM: there is already a day present on the day prior to this, please clarify symptom day(s)' (Site from DM).		15 Mar 2021 21:28:30
User entered 'Day 3 (Day 3)'	Kayla Flege (b) (4) (b) (4)	13 Dec 2020 19:06:57

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:18:19**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '13 Dec 2020'	Kayla Flege (b) (4)	13 Dec 2020 19:06:57
	(b) (4)	

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '0'	Kayla Flege (b) (4) (b) (4)	13 Dec 2020 19:06:57

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '99'	Kayla Flege (b) (4) (b) (4)	13 Dec 2020 19:06:57

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User entered '%'	System	13 Dec 2020 19:06:57



**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:18:19**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '98.5' F	Kayla Flege (b) (4) (b) (4)	13 Dec 2020 19:06:57

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:19

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Kayla Flege (b) (4)	13 Dec 2020 19:06:57
	(b) (4)	

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	13 Dec 2020 19:06:57

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	13 Dec 2020 19:06:57

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	13 Dec 2020 19:06:57

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Kayla Flege (b) (4)	13 Dec 2020 19:06:57
	(b) (4)	

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	13 Dec 2020 19:06:57

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:18:19**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Kayla Flege (b) (4)	13 Dec 2020 19:06:57
	(b) (4)	



US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	13 Dec 2020 19:06:57

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:18:19**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	13 Dec 2020 19:06:57

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:19

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	13 Dec 2020 19:06:57

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:18:19**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'Mild (Mild)'	Kayla Flege (b) (4) (b) (4)	13 Dec 2020 19:06:57

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	13 Dec 2020 19:06:57

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (4)**

**Generated On: 11 Aug 2021 22:18:19**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	13 Dec 2020 19:06:57

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	13 Dec 2020 19:06:57

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	13 Dec 2020 19:06:57



US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:18:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Kayla Flege (b) (4) (b) (4)	13 Dec 2020 19:06:57

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 22:49:02
User entered 'Day 4 (Day 4)'	Whitney West (b) (4)	14 Dec 2020 17:26:11

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:18:19**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '14 Dec 2020'	Whitney West (b) (4)	14 Dec 2020 17:26:11

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:18:19**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '0'	Whitney West (b) (4)	14 Dec 2020 17:26:11

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:18:19**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '97'	Whitney West (b) (4)	14 Dec 2020 17:26:11

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:18:19**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User entered '%'	System	14 Dec 2020 17:26:11

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '97.3' F	Whitney West (b) (4)	14 Dec 2020 17:26:11

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:18:19**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	14 Dec 2020 17:26:11



US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	14 Dec 2020 17:26:11

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	14 Dec 2020 17:26:11

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	14 Dec 2020 17:26:11

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:18:19**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	14 Dec 2020 17:26:11

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	14 Dec 2020 17:26:11

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	14 Dec 2020 17:26:11

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	14 Dec 2020 17:26:11

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:18:19**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	14 Dec 2020 17:26:11



**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:18:19**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	14 Dec 2020 17:26:11

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:18:19**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'Mild (Mild)'	Whitney West (b) (4)	14 Dec 2020 17:26:11

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	14 Dec 2020 17:26:11

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:18:19**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	14 Dec 2020 17:26:11

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	14 Dec 2020 17:26:11

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:18:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	14 Dec 2020 17:26:11

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:18:19**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	14 Dec 2020 17:26:11

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 22:49:02
User entered 'Day 5 (Day 5)'	Whitney West (b) (4)	15 Dec 2020 15:45:54



**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '15 Dec 2020'	Whitney West (b) (4)	15 Dec 2020 15:45:54

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '0'	Whitney West (b) (4)	15 Dec 2020 15:45:54

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:18:19**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '100'	Whitney West (b) (4)	15 Dec 2020 15:45:54

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User entered '%'	System	15 Dec 2020 15:45:54

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '98.2' F	Whitney West (b) (4)	15 Dec 2020 15:45:54

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	15 Dec 2020 15:45:54

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	15 Dec 2020 15:45:54

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	15 Dec 2020 15:45:54



US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	15 Dec 2020 15:45:54

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	15 Dec 2020 15:45:54

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:19

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	15 Dec 2020 15:45:54

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	15 Dec 2020 15:45:54

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	15 Dec 2020 15:45:54

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	15 Dec 2020 15:45:54

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:18:19**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	15 Dec 2020 15:45:54

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'Mild (Mild)'	Whitney West (b) (4)	15 Dec 2020 15:45:54



US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	15 Dec 2020 15:45:54

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	15 Dec 2020 15:45:54

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	15 Dec 2020 15:45:54

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:18:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	15 Dec 2020 15:45:54

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	15 Dec 2020 15:45:54

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 22:49:02
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Whitney West (b) (4)	17 Dec 2020 20:18:23
User entered empty.	Whitney West (b) (4)	17 Dec 2020 20:17:59

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:19

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 20:18:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Dec 2020 20:18:23
User entered '16 Dec 2020' reason for change: Data Entry Error	Whitney West (b) (4)	17 Dec 2020 20:18:23
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Dec 2020 20:17:59
User entered empty.	Whitney West (b) (4)	17 Dec 2020 20:17:59

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User closed query 'Per CDM: It appears that entire data for Day 6 and O2 Saturation & Temperature for Day 8 were not provided. If not collected, please consider recording as 'Not Done'. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 10:01:46
Query 'Per CDM: It appears that entire data for Day 6 and O2 Saturation & Temperature for Day 8 were not provided. If not collected, please consider recording as 'Not Done'. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 22:55:50
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Jan 2021 22:52:01
User opened query 'Per CDM: It appears that entire data for Day 6 and O2 Saturation & Temperature for Day 8 were not provided. If not collected, please consider recording as 'Not Done'. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 18:55:38
User entered '0'	Whitney West (b) (4) (b) (4)	17 Dec 2020 20:17:59



US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered empty.	Whitney West (b) (4)	17 Dec 2020 20:17:59

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User entered empty.	System	17 Dec 2020 20:17:59

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered empty.	Whitney West (b) (4)	17 Dec 2020 20:17:59

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered empty.	Whitney West (b) (4)	17 Dec 2020 20:17:59

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered empty.	Whitney West (b) (4)	17 Dec 2020 20:17:59

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered empty.	Whitney West (b) (4)	17 Dec 2020 20:17:59

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered empty.	Whitney West (b) (4)	17 Dec 2020 20:17:59

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered empty.	Whitney West (b) (4)	17 Dec 2020 20:17:59



**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered empty.	Whitney West (b) (4)	17 Dec 2020 20:17:59

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered empty.	Whitney West (b) (4)	17 Dec 2020 20:17:59

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered empty.	Whitney West (b) (4)	17 Dec 2020 20:17:59

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered empty.	Whitney West (b) (4)	17 Dec 2020 20:17:59

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:18:19**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered empty.	Whitney West (b) (4)	17 Dec 2020 20:17:59

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:19

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered empty.	Whitney West (b) (4)	17 Dec 2020 20:17:59

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered empty.	Whitney West (b) (4)	17 Dec 2020 20:17:59

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered empty.	Whitney West (b) (4)	17 Dec 2020 20:17:59



US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered empty.	Whitney West (b) (4)	17 Dec 2020 20:17:59

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered empty.	Whitney West (b) (4)	17 Dec 2020 20:17:59

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:18:19

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered empty.	Whitney West (b) (4)	17 Dec 2020 20:17:59

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 22:49:02
User entered 'Day 7 (Day 7)'	Whitney West (b) (4)	17 Dec 2020 20:17:59

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:18:19**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '17 Dec 2020'	Whitney West (b) (4)	17 Dec 2020 20:17:59

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:19

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '0'	Whitney West (b) (4)	17 Dec 2020 20:17:59

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:19

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '99'	Whitney West (b) (4)	17 Dec 2020 20:17:59

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:18:19**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User entered '%'	System	17 Dec 2020 20:17:59



US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:19

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '98.2' F	Whitney West (b) (4)	17 Dec 2020 20:17:59

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:18:19**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	17 Dec 2020 20:17:59

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	17 Dec 2020 20:17:59

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	17 Dec 2020 20:17:59

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	17 Dec 2020 20:17:59

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:18:19**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	17 Dec 2020 20:17:59

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:18:19**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	17 Dec 2020 20:17:59

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:19

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	17 Dec 2020 20:17:59



**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:18:19**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	17 Dec 2020 20:17:59

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:19

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	17 Dec 2020 20:17:59

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:18:19**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	17 Dec 2020 20:17:59

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:18:19**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	17 Dec 2020 20:17:59

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	17 Dec 2020 20:17:59

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:18:19**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	17 Dec 2020 20:17:59

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	17 Dec 2020 20:17:59

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:18:19

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	17 Dec 2020 20:17:59



**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:18:19**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	17 Dec 2020 20:17:59

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:19

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 22:49:02
User entered 'Day 8 (Day 8)'	Whitney West (b) (4)	18 Dec 2020 16:02:56

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:18:19**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '18 Dec 2020'	Whitney West (b) (4)	18 Dec 2020 16:02:56

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:18:19**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered '0'	Whitney West (b) (4)	18 Dec 2020 16:02:56

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:18:19**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered empty.	Whitney West (b) (4)	18 Dec 2020 16:02:56

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:19

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User entered empty.	System	18 Dec 2020 16:02:56

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:18:19**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered empty.	Whitney West (b) (4)	18 Dec 2020 16:02:56

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:18:19**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	18 Dec 2020 16:02:56



US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:19

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	18 Dec 2020 16:02:56

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:19

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	18 Dec 2020 16:02:56

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:19

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	18 Dec 2020 16:02:56

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:19

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	18 Dec 2020 16:02:56

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:18:19**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	18 Dec 2020 16:02:56

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:18:19**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	18 Dec 2020 16:02:56

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:19

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	18 Dec 2020 16:02:56

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:18:19**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	18 Dec 2020 16:02:56



**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:18:19**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	18 Dec 2020 16:02:56

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:18:19**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	18 Dec 2020 16:02:56

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:19

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	18 Dec 2020 16:02:56

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:18:19**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	18 Dec 2020 16:02:56

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:18:19

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	18 Dec 2020 16:02:56

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:18:19**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	18 Dec 2020 16:02:56

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: Symptom Log (9)**

**Generated On: 11 Aug 2021 22:18:19**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:24:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:01
User entered 'None (None)'	Whitney West (b) (4)	18 Dec 2020 16:02:56

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:18:19**

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:07
User entered '10 Dec 2020'	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 00:00:04



**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:18:19**

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:07
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 00:00:04

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:18:19**

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:07
User entered 'No (N)'	Kayla Flege (b) (4)	11 Dec 2020 00:00:04
	(b) (4)	

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:18:19**

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:07
User entered '10 Dec 2020'	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 00:00:04

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:18:19

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:07
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 00:00:04

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:18:19

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:07
User entered empty.	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 00:00:04

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:18:19**

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:07
User entered 'No (N)'	Kayla Flege (b) (4)	11 Dec 2020 00:00:04
	(b) (4)	

US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:18:19

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:07
User entered empty.	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 00:00:04

**US3272291**

**Folder: Covid-19 Assessment 10 Dec 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:18:19**

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:07
User entered empty.	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 00:00:04



US3272291

Folder: Covid-19 Assessment 10 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:18:19

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:19:21
User entered '0'	System	11 Dec 2020 00:00:04

**US3272291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:54

**US3272291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:05
User entered 'Yes (Y)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:54

**US3272291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:05
User closed query 'Per GCL Lab Reconciliation: Saliva : Sample dated 14DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).		28 Dec 2020 08:10:52
Query 'Per GCL Lab Reconciliation: Saliva : Sample dated 14DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'updated' (Site from DM).	Kayla Flege (b) (4)	24 Dec 2020 19:14:56
User opened query 'Per GCL Lab Reconciliation: Saliva : Sample dated 14DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 08:16:10
Query 'US3272291 ' canceled (Site from DM).		24 Dec 2020 08:16:06
User opened query 'US3272291 ' (Site from DM).		24 Dec 2020 08:16:02
User entered '12 Dec 2020'	Andrea Clement (b) (4)	12 Dec 2020 22:47:54

**US3272291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:54

**US3272291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Flege (b) (4)	24 Dec 2020 19:15:13
User entered 'No (N)'	Andrea Clement (b) (4)	12 Dec 2020 22:47:54

**US3272291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:05
User entered '14 Dec 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	24 Dec 2020 19:15:13
User entered empty.	Andrea Clement (b) (4)	12 Dec 2020 22:47:54

**US3272291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:18:19**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:54



**US3272291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:18:19**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Flege (b) (4)	24 Dec 2020 19:15:28
User entered 'No (N)'	Andrea Clement (b) (4)	12 Dec 2020 22:47:54

US3272291

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:18:19

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
User closed query 'Per GCL Lab Reconciliation Requery: Saliva: Per response, since the sample is still missing in PPD. Please provide the Accession number and tracking number with shipping date in the response as the information is needed for the tracking the sample in PPD' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 12:53:44
Query 'Per GCL Lab Reconciliation Requery: Saliva: Per response, since the sample is still missing in PPD. Please provide the Accession number and tracking number with shipping date in the response as the information is needed for the tracking the sample in PPD' answered with 'sample was shipped' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 21:50:51
User opened query 'Per GCL Lab Reconciliation Requery: Saliva: Per response, since the sample is still missing in PPD. Please provide the Accession number and tracking number with shipping date in the response as the information is needed for the tracking the sample in PPD' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 10:05:48
User closed query 'Per GCL Lab Reconciliation Requery 2: Saliva: Per your response, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).		22 Jan 2021 10:05:48
DataPoint Verified.		20 Jan 2021 21:44:05
Query 'Per GCL Lab Reconciliation Requery 2: Saliva: Per your response, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' answered with 'sample shipped' (Site from DM).		13 Jan 2021 14:35:08
User opened query 'Per GCL Lab Reconciliation Requery 2: Saliva: Per your response, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).		11 Jan 2021 06:56:12

US3272291

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:18:19

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Requery 1: Please confirm if the saliva samples were sent to PPD central lab.Thanks ? ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 06:56:12
Query 'Per GCL Lab Reconciliation: Saliva: Requery 1: Please confirm if the saliva samples were sent to PPD central lab.Thanks ? ' answered with 'sent to ppd' (Site from DM).		07 Jan 2021 23:03:29
User opened query 'Per GCL Lab Reconciliation: Saliva: Requery 1: Please confirm if the saliva samples were sent to PPD central lab.Thanks ? ' (Site from DM).		04 Jan 2021 08:19:55
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16DEC2020 is recorded under Illness Visit Day 7 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).		04 Jan 2021 08:19:55
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16DEC2020 is recorded under Illness Visit Day 7 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 'date correct' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 23:06:47
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16DEC2020 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 07:08:10
User entered '16 Dec 2020' reason for change: Data Entry Error	Kayla Flege (b) (4)	24 Dec 2020 19:15:28
User entered empty.	Andrea Clement (b) (4)	12 Dec 2020 22:47:54

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1834 of 2134

**US3272291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:18:19**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:54

**US3272291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:18:19**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:05
User entered 'No (N)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:54

**US3272291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:18:19**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:05
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:54

**US3272291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 22:18:19**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:54

**US3272291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 22:18:19**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:05
User entered 'No (N)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:54



**US3272291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 22:18:19**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:05
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:54

**US3272291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:54

**US3272291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:05
User entered 'No (N)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:54

**US3272291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:05
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:54

**US3272291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:54

**US3272291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:05
User entered 'No (N)'	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:54

**US3272291**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:05
User entered empty.	Andrea Clement (b) (4) (b) (4)	12 Dec 2020 22:47:54

**US3272291**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:24
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 00:00:12



**US3272291**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:24
User entered '10 Dec 2020'	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 00:00:12

**US3272291**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:24
User entered 'Clinic (Clinic)'	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 00:00:12

**US3272291**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	11 Dec 2020 00:00:12

**US3272291**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:31
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 00:00:50

US3272291

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:18:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:31
User entered '10 Dec 2020'	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 00:00:50

**US3272291**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:31
User entered '17:25'	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 00:00:50

**US3272291**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Dec 2020 17:25'	System	11 Dec 2020 00:00:50

**US3272291**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:31
User entered '177.2' cm	Kayla Flege (b) (4)	11 Dec 2020 00:00:50
DataPoint set to visible.	(b) (4) System	11 Dec 2020 00:00:12



**US3272291**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Weight \(.xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:31
User entered '113.2' kg	Kayla Flege (b) (4)	11 Dec 2020 00:00:50
DataPoint set to visible.	(b) (4) System	11 Dec 2020 00:00:12

**US3272291**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:31
User entered '36.5' C	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 00:00:50

**US3272291**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:31
User entered 'Oral (Oral)'	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 00:00:50

**US3272291**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:31
User entered empty.	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 00:00:50

**US3272291**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:31
User entered '78'	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 00:00:50

**US3272291**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Dec 2020 00:00:50

**US3272291**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:31
User entered '16'	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 00:00:50

**US3272291**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Dec 2020 00:00:50



**US3272291**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:31
User entered '122'	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 00:00:50

**US3272291**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Dec 2020 00:00:50

**US3272291**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:31
User entered '78'	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 00:00:50

**US3272291**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Dec 2020 00:00:50

**US3272291**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:18:19**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:37
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 00:01:00

**US3272291**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:18:19**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:37
User entered '10 Dec 2020'	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 00:01:00

**US3272291**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 22:18:19**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:43
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 00:01:06

US3272291

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:18:19

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:43:43
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 10 DEC 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum 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).		21 Dec 2020 09:40:00
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 10 DEC 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum 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 'all samples have been shipped' (Site from DM).	Kayla Flege (b) (4) (b) (4)	18 Dec 2020 22:54:15
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 10 DEC 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 12:34:18
User entered '10 Dec 2020'	Kayla Flege (b) (4) (b) (4)	11 Dec 2020 00:01:06



**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:21
User entered 'Yes (Y)'		20 Jan 2021 16:31:19

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:21
User entered '14 Jan 2021'		20 Jan 2021 16:31:19

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:21
User entered 'Clinic (Clinic)'		20 Jan 2021 16:31:19

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User entered 'UNBLND_DECIDE'	System	20 Jan 2021 16:31:19

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:18:19**

**Date of updated informed consent (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:25
User entered '14 Jan 2021'		20 Jan 2021 16:32:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:18:19**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:41:40

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:18:19**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:25
User entered 'Yes (Y)'		20 Jan 2021 16:32:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:18:19**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:40:27
User closed query 'PER CDM: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 15:04:14
Query 'PER CDM: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' answered with 'Data corrected' (Site from DM).		08 Apr 2021 17:37:38
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error		08 Apr 2021 17:37:13
User opened query 'PER CDM: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' (Site from DM).		08 Apr 2021 12:58:50
User entered 'AMENDMENT 5 (AMENDMENT 5)'		10 Mar 2021 16:55:28
WR# 5295537	System	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:41:40



**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:18:19**

**Date of unblinding (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:25
User entered '14 Jan 2021'		20 Jan 2021 16:32:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:18:19**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:25
User entered 'Placebo (Placebo)'		20 Jan 2021 16:32:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:18:19**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:25
User entered 'Placebo (Placebo)'		20 Jan 2021 16:32:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:18:19**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:25
User entered 'Placebo (Placebo)'		20 Jan 2021 16:32:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:18:19**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:25
User entered 'Yes (Y)'		20 Jan 2021 16:32:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:18:19**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User entered '1'	System	20 Jan 2021 16:32:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:18:19**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User entered 'I'	System	20 Jan 2021 16:32:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:18:19**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:30
User entered missing code ND - Not Done.		20 Jan 2021 16:34:14



**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:18:19**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:30
User entered missing code ND - Not Done.		20 Jan 2021 16:34:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:18:19**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User entered empty.	System	20 Jan 2021 16:34:14
DataPoint set to visible.	System	20 Jan 2021 16:32:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:18:19**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:30
User entered missing code ND - Not Done.		20 Jan 2021 16:34:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:18:19**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:30
User entered missing code ND - Not Done.		20 Jan 2021 16:34:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:18:19**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User entered empty.	System	20 Jan 2021 16:34:14
DataPoint set to visible.	System	20 Jan 2021 16:32:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User accepted default value 'Pre-Dose (PREDOSE)'		20 Jan 2021 16:34:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:30
User entered 'Yes (Y)'		20 Jan 2021 16:34:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:30
User entered '14 Jan 2021'		20 Jan 2021 16:34:14



**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:30
User entered '17:08'		20 Jan 2021 16:34:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User entered '14 Jan 2021 17:08'	System	20 Jan 2021 16:34:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:30
User entered '36.6' C		20 Jan 2021 16:34:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:30
User entered 'Oral (Oral)'		20 Jan 2021 16:34:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:30
User entered empty.		20 Jan 2021 16:34:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:30
User entered '80'		20 Jan 2021 16:34:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User entered 'bpm'	System	20 Jan 2021 16:34:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:30
User entered '16'		20 Jan 2021 16:34:14



**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User entered 'breaths/min'	System	20 Jan 2021 16:34:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:30
User entered '136'		20 Jan 2021 16:34:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User entered 'mmHg'	System	20 Jan 2021 16:34:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:30
User entered '82'		20 Jan 2021 16:34:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User entered 'mmHg'	System	20 Jan 2021 16:34:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:18:19**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:30
User entered missing code ND - Not Done.		20 Jan 2021 16:34:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:18:19**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:30
User entered missing code ND - Not Done.		20 Jan 2021 16:34:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:18:19**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User entered empty.	System	20 Jan 2021 16:34:14
DataPoint set to visible.	System	20 Jan 2021 16:32:14



**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User accepted default value 'Post-Dose (POSTDOSE)'		20 Jan 2021 16:35:04

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:30
User entered 'Yes (Y)'		20 Jan 2021 16:35:04

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:30
User entered '14 Jan 2021'		20 Jan 2021 16:35:04

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:30
User entered '18:11'		20 Jan 2021 16:35:04

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User entered '14 Jan 2021 18:11'	System	20 Jan 2021 16:35:04

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:30
User entered '36.8' C		20 Jan 2021 16:35:04

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:30
User entered 'Oral (Oral)'		20 Jan 2021 16:35:04

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:30
User entered empty.		20 Jan 2021 16:35:04



**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:30
User entered '76'		20 Jan 2021 16:35:04

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User entered 'bpm'	System	20 Jan 2021 16:35:04

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:30
User entered '14'		20 Jan 2021 16:35:04

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User entered 'breaths/min'	System	20 Jan 2021 16:35:04

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:30
User entered '128'		20 Jan 2021 16:35:04

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User entered 'mmHg'	System	20 Jan 2021 16:35:04

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:30
User entered '76'		20 Jan 2021 16:35:04

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User entered 'mmHg'	System	20 Jan 2021 16:35:04



**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:18:19**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:34
User entered 'Yes (Y)'		20 Jan 2021 16:35:50

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:18:19**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:34
User entered '14 Jan 2021'		20 Jan 2021 16:35:50

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:18:19**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:38
User entered 'Yes (Y)'		20 Jan 2021 16:36:18

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:18:19**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:38
User entered empty.		20 Jan 2021 16:36:18

US3272291

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:19

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)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:38
User entered empty.		20 Jan 2021 16:36:18

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:18:19**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User entered 'mRNA-1273'	System	20 Jan 2021 16:36:18
DataPoint set to visible.	System	20 Jan 2021 16:32:14

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:18:19**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:38
User entered '14 Jan 2021'		20 Jan 2021 16:36:18

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:18:19**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:38
User entered '17:37'		20 Jan 2021 16:36:18



**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:18:19**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User entered '14 Jan 2021 17:37'	System	20 Jan 2021 16:36:18

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:18:19**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:38
User entered 'Left Arm (LEFT ARM)'		20 Jan 2021 16:36:18

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:18:19**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
DataPoint Verified.		20 Jan 2021 21:44:38
User entered 'ONCE'	System	20 Jan 2021 16:36:18

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:18:19**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User entered 'INTRAMUSCULAR'	System	20 Jan 2021 16:36:18

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:18:19**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:42
User entered 'Yes (Y)'		20 Jan 2021 16:32:56

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:18:19**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:42
User entered '14 Jan 2021'		20 Jan 2021 16:32:56

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:18:19**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:42
User entered '16:51'		20 Jan 2021 16:32:56

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:18:19**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User entered '14 Jan 2021 16:51'	System	20 Jan 2021 16:32:56



**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:18:19**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:46
User entered 'Yes (Y)'		20 Jan 2021 16:33:11

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:18:19**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:46
User entered '14 Jan 2021'		20 Jan 2021 16:33:11

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:18:19**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:46
User entered '16:57'		20 Jan 2021 16:33:11

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:18:19**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User entered '14 Jan 2021 16:57'	System	20 Jan 2021 16:33:11

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 21:44:59
User entered 'Yes (Y)'		20 Jan 2021 16:33:15

**US3272291**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:26:39
User entered 'I'	System	20 Jan 2021 16:33:15

**US3272291**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:41:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 14:18:40

**US3272291**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:41:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '21 Jan 2021'	(b) (4), (b) (6)	22 Jan 2021 14:18:40



**US3272291**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:41:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Jan 2021 14:18:40

**US3272291**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:41:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	22 Jan 2021 14:18:40

**US3272291**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:41:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Jan 2021 14:18:48

**US3272291**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:41:17
User entered 'I'	System	22 Jan 2021 14:18:48

**US3272291**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:41:17
User entered '1'	System	22 Jan 2021 14:18:48
DataPoint set to visible.	System	22 Jan 2021 14:18:48

**US3272291**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 15:32:23

**US3272291**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '08 Feb 2021'	(b) (4), (b) (6)	11 Feb 2021 15:32:23

**US3272291**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Feb 2021 15:32:23



**US3272291**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User entered 'OLD29'	System	11 Feb 2021 15:32:23

**US3272291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User accepted default value 'Pre-Dose (PREDOSE)'		11 Feb 2021 15:33:23

**US3272291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 15:33:23

**US3272291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '08 Feb 2021'	(b) (4), (b) (6)	11 Feb 2021 15:33:23

**US3272291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '16:08'	(b) (4), (b) (6)	11 Feb 2021 15:33:23

**US3272291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User entered '08 Feb 2021 16:08'	System	11 Feb 2021 15:33:23

**US3272291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '36.8' C	(b) (4), (b) (6)	11 Feb 2021 15:33:23

**US3272291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Feb 2021 15:33:23



**US3272291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 15:33:23

**US3272291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '61'	(b) (4), (b) (6)	11 Feb 2021 15:33:23

**US3272291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User entered 'bpm'	System	11 Feb 2021 15:33:23

**US3272291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '14'	(b) (4), (b) (6)	11 Feb 2021 15:33:23

**US3272291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User entered 'breaths/min'	System	11 Feb 2021 15:33:23

**US3272291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '138'	(b) (4), (b) (6)	11 Feb 2021 15:33:23

US3272291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User entered 'mmHg'	System	11 Feb 2021 15:33:23

**US3272291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '80'	(b) (4), (b) (6)	11 Feb 2021 15:33:23



US3272291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:18:19

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User entered 'mmHg'	System	11 Feb 2021 15:33:23

**US3272291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User accepted default value 'Post-Dose (POSTDOSE)'		11 Feb 2021 15:35:25

**US3272291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'No (N)'	(b) (4), (b) (6)	11 Feb 2021 15:35:25

**US3272291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 15:35:25

**US3272291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 15:35:25

**US3272291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User entered empty.	System	11 Feb 2021 15:35:25

**US3272291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 15:35:25

**US3272291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 15:35:25



**US3272291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 15:35:25

**US3272291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 15:35:25

**US3272291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User entered empty.	System	11 Feb 2021 15:35:25

**US3272291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 15:35:25

US3272291

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:18:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User entered empty.	System	11 Feb 2021 15:35:25

**US3272291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 15:35:25

**US3272291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User entered empty.	System	11 Feb 2021 15:35:25

**US3272291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 15:35:25



**US3272291**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:18:19**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User entered empty.	System	11 Feb 2021 15:35:25

**US3272291**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:18:19**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 15:35:37

**US3272291**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:18:19**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '08 Feb 2021'	(b) (4), (b) (6)	11 Feb 2021 15:35:37

**US3272291**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:18:19**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'No (N)'	(b) (4), (b) (6)	11 Feb 2021 15:36:56

**US3272291**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:18:19**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	(b) (4), (b) (6)	11 Feb 2021 15:36:56

US3272291

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:19

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)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Full body hives after 1st dose- see AE'	(b) (4), (b) (6)	11 Feb 2021 15:36:56

**US3272291**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:18:19**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User entered empty.	System	11 Feb 2021 15:36:56
DataPoint set to visible.	System	22 Jan 2021 14:18:48

**US3272291**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:18:19**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 15:36:56



**US3272291**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:18:19**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 15:36:56

US3272291

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:19

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User entered empty.	System	11 Feb 2021 15:36:56

**US3272291**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:18:19**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	(b) (4), (b) (6)	11 Feb 2021 15:36:56

US3272291

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:19

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User entered empty.	System	11 Feb 2021 15:36:56

US3272291

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:18:19

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User entered empty.	System	11 Feb 2021 15:36:56

US3272291

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:18:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
User closed query 'Per GCL Lab Recon: Immuno: Per Preclarus report, Sample dated 13 MAR 2021 is recorded under OL- 3 visit in PPD GCL, however the same is missing in OL-D57 in EDC. Please review and update the sample data in EDC as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 21:39:24
Query 'Per GCL Lab Recon: Immuno: Per Preclarus report, Sample dated 13 MAR 2021 is recorded under OL- 3 visit in PPD GCL, however the same is missing in OL-D57 in EDC. Please review and update the sample data in EDC as appropriate. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 22:55:42
User opened query 'Per GCL Lab Recon: Immuno: Per Preclarus report, Sample dated 13 MAR 2021 is recorded under OL- 3 visit in PPD GCL, however the same is missing in OL-D57 in EDC. Please review and update the sample data in EDC as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 10:26:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Feb 2021 15:37:04

**US3272291**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:44:06
User entered 'I'	System	11 Feb 2021 15:37:04

**US3272291**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	Ashley Bell (b) (4)	30 Mar 2021 18:04:49



**US3272291**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '16 Feb 2021'	Ashley Bell (b) (4)	30 Mar 2021 18:04:49

**US3272291**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Contact Made (CONTACT MADE)'	Ashley Bell (b) (4)	30 Mar 2021 18:04:49

**US3272291**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:18:19**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 18:04:49

**US3272291**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	Ashley Bell (b) (4)	30 Mar 2021 18:04:54

**US3272291**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:18:19**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:25
User entered 'I'	System	30 Mar 2021 18:04:54

**US3272291**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:28:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	Ashley Bell (b) (4)	30 Mar 2021 18:05:30

**US3272291**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:28:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '13 Mar 2021'	Ashley Bell (b) (4)	30 Mar 2021 18:05:30

**US3272291**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:28:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Clinic (Clinic)'	Ashley Bell (b) (4)	30 Mar 2021 18:05:30



**US3272291**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:18:19**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:28:13
User entered 'OLD57'	System	30 Mar 2021 18:05:30

**US3272291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:28:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	Ashley Bell (b) (4)	30 Mar 2021 18:16:35

**US3272291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:28:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '13 Mar 2021'	Ashley Bell (b) (4)	30 Mar 2021 18:16:35

**US3272291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:28:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '10:56'	Ashley Bell (b) (4)	30 Mar 2021 18:16:35

**US3272291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:28:13
User entered '13 Mar 2021 10:56'	System	30 Mar 2021 18:16:35

**US3272291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:28:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '36.7' C	Ashley Bell (b) (4)	30 Mar 2021 18:16:35

**US3272291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:28:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Oral (Oral)'	Ashley Bell (b) (4)	30 Mar 2021 18:16:35

**US3272291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:28:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered empty.	Ashley Bell (b) (4)	30 Mar 2021 18:16:35



**US3272291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:28:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '71'	Ashley Bell (b) (4)	30 Mar 2021 18:16:35

**US3272291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:28:13
User entered 'bpm'	System	30 Mar 2021 18:16:35

**US3272291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:28:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '15'	Ashley Bell (b) (4)	30 Mar 2021 18:16:35

**US3272291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:28:13
User entered 'breaths/min'	System	30 Mar 2021 18:16:35

**US3272291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:28:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '139'	Ashley Bell (b) (4)	30 Mar 2021 18:16:35

**US3272291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:28:13
User entered 'mmHg'	System	30 Mar 2021 18:16:35

**US3272291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:28:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '82'	Ashley Bell (b) (4)	30 Mar 2021 18:16:35

**US3272291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:28:13
User entered 'mmHg'	System	30 Mar 2021 18:16:35



**US3272291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:28:13

**US3272291**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:18:19**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:28:13

**US3272291**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:18:19**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:28:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	Ashley Bell (b) (4)	30 Mar 2021 18:05:39

**US3272291**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:18:19**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:28:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '13 Mar 2021'	Ashley Bell (b) (4)	30 Mar 2021 18:05:39

**US3272291**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:18:19**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:28:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered 'Yes (Y)'	Ashley Bell (b) (4)	30 Mar 2021 18:15:49

**US3272291**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:18:19**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:28:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '13 Mar 2021'	Ashley Bell (b) (4)	30 Mar 2021 18:15:49

**US3272291**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:18:19**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:28:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:36:19
User entered '11:08'	Ashley Bell (b) (4)	30 Mar 2021 18:15:49

**US3272291**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:18:19**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:28:13
User entered '13 Mar 2021 11:08'	System	30 Mar 2021 18:15:49



US3272291

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:18:19

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:12:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
User closed query 'Per DM CLR: Per Safety Follow-up Diary Day 152, Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM). Query 'Per DM CLR: Per Safety Follow-up Diary Day 152, Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'Subject had hives after his first dose of vaccine. It is noted in AE. ' (Site from DM). User opened query 'Per DM CLR: Per Safety Follow-up Diary Day 152, Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:56:45
	Whitney West (b) (4)	14 Apr 2021 21:30:04
	(b) (4), (b) (6)	02 Apr 2021 18:56:19
	(b) (4), (b) (6)	20 Jan 2021 21:49:01
User entered 'Yes (Y)'	Whitney West (b) (4)	18 Dec 2020 15:59:38

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47

US3272291

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:18:19

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Hives - version MedDRA\\23.0.	Coder Import (b) (4)	11 Feb 2021 21:00:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Feb 2021 21:00:57
Data point term sent to Coder	System	08 Feb 2021 23:56:02
User entered 'Hives, fully body'	Whitney West (b) (4)	08 Feb 2021 23:55:02

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'No (N)'	Whitney West (b) (4)	08 Feb 2021 23:55:02

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'No (N)'	Whitney West (b) (4)	08 Feb 2021 23:55:02

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'No (N)'	Whitney West (b) (4)	08 Feb 2021 23:55:02

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '15 Jan 2021'	Whitney West (b) (4)	08 Feb 2021 23:55:02

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Feb 2021 16:56:24
User entered '15:00' reason for change: Per Query Resolution	Whitney West (b) (4)	09 Feb 2021 16:56:24
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Feb 2021 23:55:02
User entered empty.	Whitney West (b) (4)	08 Feb 2021 23:55:02



**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User entered '15 Jan 2021 15:00'	System	09 Feb 2021 16:56:24
User entered empty.	System	08 Feb 2021 23:55:02

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'No (N)'	Whitney West (b) (4)	08 Feb 2021 23:55:02

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '18 Jan 2021'	Whitney West (b) (4)	08 Feb 2021 23:55:02

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Feb 2021 16:56:24
User entered '12:00' reason for change: Per Query Resolution	Whitney West (b) (4)	09 Feb 2021 16:56:24
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Feb 2021 23:55:02
User entered empty.	Whitney West (b) (4)	08 Feb 2021 23:55:02

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User entered '18 Jan 2021 12:00'	System	09 Feb 2021 16:56:24
User entered empty.	System	08 Feb 2021 23:55:02

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Whitney West (b) (4)	08 Feb 2021 23:55:02

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'No (N)'	Whitney West (b) (4)	08 Feb 2021 23:55:02

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '0'	Whitney West (b) (4)	08 Feb 2021 23:55:02



**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '0'	Whitney West (b) (4)	08 Feb 2021 23:55:02

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '0'	Whitney West (b) (4)	08 Feb 2021 23:55:02

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered empty.	Whitney West (b) (4)	08 Feb 2021 23:55:02

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered empty.	Whitney West (b) (4)	08 Feb 2021 23:55:02

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered empty.	Whitney West (b) (4)	08 Feb 2021 23:55:02

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered empty.	Whitney West (b) (4)	08 Feb 2021 23:55:02

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '0'	Whitney West (b) (4)	08 Feb 2021 23:55:02

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '0'	Whitney West (b) (4)	08 Feb 2021 23:55:02



**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '0'	Whitney West (b) (4)	08 Feb 2021 23:55:02

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'Related (RELATED)'	Whitney West (b) (4)	08 Feb 2021 23:55:02

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'Related (RELATED)'	Whitney West (b) (4)	08 Feb 2021 23:55:02

US3272291

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:18:19

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 13:46:20
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	15 Mar 2021 13:46:17
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	12 Mar 2021 23:43:18
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 23:43:05
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	12 Mar 2021 23:42:40
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 05:55:58
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Whitney West (b) (4) (b) (4)	08 Feb 2021 23:55:02

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
Signature has been broken.	Ashley Bell (b) (4)	12 Apr 2021 21:51:00
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'I'	Whitney West (b) (4)	08 Feb 2021 23:55:02

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '0'	Whitney West (b) (4)	08 Feb 2021 23:55:02

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '0'	Whitney West (b) (4)	08 Feb 2021 23:55:02

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Whitney West (b) (4)	08 Feb 2021 23:55:02



**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered empty.	Whitney West (b) (4)	08 Feb 2021 23:55:02

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered empty.	Whitney West (b) (4)	08 Feb 2021 23:55:02

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User entered '0'	System	08 Feb 2021 23:55:02

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47
User entered '0'	System	08 Feb 2021 23:55:02

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:18:19**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:50:47

US3272291

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 22:18:19

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Suspected COVID-19, LLT: Suspected COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 22:19:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 22:19:57
Data point term sent to Coder	System	12 Apr 2021 21:51:52
User entered 'suspected covid-19'	Ashley Bell (b) (4)	12 Apr 2021 21:51:48

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User entered 'Yes (Y)'	Ashley Bell (b) (4)	12 Apr 2021 21:51:48

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User entered 'No (N)'	Ashley Bell (b) (4)	12 Apr 2021 21:51:48



**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User entered 'No (N)'	Ashley Bell (b) (4)	12 Apr 2021 21:51:48

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User entered '08 Dec 2020'	Ashley Bell (b) (4)	12 Apr 2021 21:51:48

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User entered empty.	Ashley Bell (b) (4)	12 Apr 2021 21:51:48

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 21:51:48

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User entered 'No (N)'	Ashley Bell (b) (4)	12 Apr 2021 21:51:48

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User entered '17 Dec 2020'	Ashley Bell (b) (4)	12 Apr 2021 21:51:48

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User entered empty.	Ashley Bell (b) (4)	12 Apr 2021 21:51:48

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 21:51:48



**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User entered 'Grade 1/Mild (Grade 1/Mild)'	Ashley Bell (b) (4)	12 Apr 2021 21:51:48

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User entered 'No (N)'	Ashley Bell (b) (4)	12 Apr 2021 21:51:48

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User entered '0'	Ashley Bell (b) (4)	12 Apr 2021 21:51:48

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User entered '0'	Ashley Bell (b) (4)	12 Apr 2021 21:51:48

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User entered '0'	Ashley Bell (b) (4)	12 Apr 2021 21:51:48

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User entered empty.	Ashley Bell (b) (4)	12 Apr 2021 21:51:48

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User entered empty.	Ashley Bell (b) (4)	12 Apr 2021 21:51:48

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User entered empty.	Ashley Bell (b) (4)	12 Apr 2021 21:51:48



**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User entered empty.	Ashley Bell (b) (4)	12 Apr 2021 21:51:48

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User entered '0'	Ashley Bell (b) (4)	12 Apr 2021 21:51:48

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User entered '0'	Ashley Bell (b) (4)	12 Apr 2021 21:51:48

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User entered '0'	Ashley Bell (b) (4)	12 Apr 2021 21:51:48

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User entered 'Not Related (NOT RELATED)'	Ashley Bell (b) (4)	12 Apr 2021 21:51:48

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User entered 'Not Related (NOT RELATED)'	Ashley Bell (b) (4)	12 Apr 2021 21:51:48

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User entered 'Not Applicable (NOT APPLICABLE)'	Ashley Bell (b) (4)	12 Apr 2021 21:51:48

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User entered 'I'	Ashley Bell (b) (4)	12 Apr 2021 21:51:48



**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User entered '0'	Ashley Bell (b) (4)	12 Apr 2021 21:51:48

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User entered '0'	Ashley Bell (b) (4)	12 Apr 2021 21:51:48

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Ashley Bell (b) (4)	12 Apr 2021 21:51:48

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User entered empty.	Ashley Bell (b) (4)	12 Apr 2021 21:51:48

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	14 Apr 2021 19:03:34
User entered empty.	Ashley Bell (b) (4)	12 Apr 2021 21:51:48

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Apr 2021 21:51:48

**US3272291**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 22:18:19**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 21:51:48

US3272291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:18:19

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:12:59
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Flege (b) (4)	21 Nov 2020 23:38:45
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 18:53:39



US3272291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:18:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Nov 2020 23:41:08
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Nov 2020 23:41:08
	(b) (4)	
Data point term sent to Coder	System	21 Nov 2020 23:40:51
User entered 'diphenhydramine'	Kayla Flege (b) (4)	21 Nov 2020 23:39:56
	(b) (4)	

US3272291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:18:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'No (N)'	Kayla Flege (b) (4)	21 Nov 2020 23:39:56
	(b) (4)	

US3272291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:18:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening INSOMNIA should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 11:41:50
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening INSOMNIA should be recorded, and update con med indication or provide clarification. ' answered with 'nothing is worsening. ' (Site from DM).	Kayla Flege (b) (4)	09 Dec 2020 20:13:50
	(b) (4)	
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening INSOMNIA should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Dec 2020 14:27:18
User entered 'insomnia'	Kayla Flege (b) (4)	21 Nov 2020 23:39:56
	(b) (4)	

**US3272291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '25'	Kayla Flege (b) (4)	21 Nov 2020 23:39:56
	(b) (4)	

**US3272291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'mg (mg)'	Kayla Flege (b) (4)	21 Nov 2020 23:39:56
	(b) (4)	

US3272291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:18:19

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered empty.	Kayla Flege (b) (4)	21 Nov 2020 23:39:56
	(b) (4)	

US3272291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:18:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'once daily (QD)'	Kayla Flege (b) (4)	21 Nov 2020 23:39:56
	(b) (4)	

US3272291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:18:19

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered empty.	Kayla Flege (b) (4)	21 Nov 2020 23:39:56
	(b) (4)	



**US3272291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'Oral (ORAL)'	Kayla Flege (b) (4)	21 Nov 2020 23:39:56
	(b) (4)	

**US3272291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:18:19**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered empty.	Kayla Flege (b) (4)	21 Nov 2020 23:39:56
	(b) (4)	

**US3272291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '21 Sep 2020'	Kayla Flege (b) (4)	21 Nov 2020 23:39:56
	(b) (4)	

**US3272291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered '0'	Kayla Flege (b) (4)	21 Nov 2020 23:39:56
	(b) (4)	

**US3272291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'Yes (Y)'	Kayla Flege (b) (4)	21 Nov 2020 23:39:56
	(b) (4)	

**US3272291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:18:19**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered empty.	Kayla Flege (b) (4)	21 Nov 2020 23:39:56
	(b) (4)	

US3272291

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:18:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:42:05
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Nov 2020 23:40:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Nov 2020 23:40:08
User entered 'No (N)' reason for change: Data Entry Error	Kayla Flege (b) (4)	21 Nov 2020 23:40:08
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Nov 2020 23:39:56
User entered empty.	Kayla Flege (b) (4)	21 Nov 2020 23:39:56
	(b) (4)	

**US3272291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Nov 2020 23:39:56



**US3272291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Nov 2020 23:39:56

**US3272291**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:18:19**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Nov 2020 23:39:56

US3272291

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 22:18:19**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Adam Brosz (b) (4)	09 Apr 2021 15:09:28
User entered 'No (N)'	Ashley Bell (b) (4)	30 Mar 2021 18:16:48

US3272291

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:18:19

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:01:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	16 Apr 2021 14:01:50
User closed query 'Per CDM: Response noted however, 'Dosing Discontinuation eCRF should only be used to indicate dosing discontinuation from Part A of the study. As subject received both doses of study drug (V1 - 22AUG2020 and V2 - 23SEP2020) please consider to remove data/clear form as per the previous query.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 14:01:45
Query 'Data is required. Please complete.' answered with 'updated ' (Site from System).	Ashley Bell (b) (4)	15 Apr 2021 20:35:11
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Apr 2021 20:35:04
User entered empty; reason for change Data Entry Error	Ashley Bell (b) (4)	15 Apr 2021 20:35:04
Query 'Per CDM: Response noted however, 'Dosing Discontinuation eCRF should only be used to indicate dosing discontinuation from Part A of the study. As subject received both doses of study drug (V1 - 22AUG2020 and V2 - 23SEP2020) please consider to remove data/clear form as per the previous query.' answered with 'Those vaccines were placebo doses. The actual Vaccine was given at OL-1 on 14JAN2021' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 21:50:23
User opened query 'Per CDM: Response noted however, 'Dosing Discontinuation eCRF should only be used to indicate dosing discontinuation from Part A of the study. As subject received both doses of study drug (V1 - 22AUG2020 and V2 - 23SEP2020) please consider to remove data/clear form as per the previous query.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 12:04:29
User closed query 'Per CDM: As per IRT and EDC subject received both doses in IRT and EDC and is not a dosing discontinuation. Please remove data/clear form.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 12:04:29

US3272291

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:18:19

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per CDM: As per IRT and EDC subject received both doses in IRT and EDC and is not a dosing discontinuation. Please remove data/clear form.' answered with 'This for the dosing at prat b of the study as subject will not be receiving ol-2 vaccination due to a anaphylaxis reaction to ol-1 vaccination' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:43:18
User opened query 'Per CDM: As per IRT and EDC subject received both doses in IRT and EDC and is not a dosing discontinuation. Please remove data/clear form.' (Site from DM).		07 Apr 2021 16:40:27
User entered '8 Feb 2021'		12 Mar 2021 23:42:40

US3272291

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:18:19

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:01:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	16 Apr 2021 14:01:48
Query 'Data is required. Please complete.' answered with 'updated' (Site from System).	Ashley Bell (b) (4)	15 Apr 2021 20:35:15
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Apr 2021 20:35:04
User entered empty; reason for change Data Entry Error	Ashley Bell (b) (4)	15 Apr 2021 20:35:04
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 23:43:28
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'		12 Mar 2021 23:42:40

US3272291

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:18:19

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:01:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 23:35:35
User entered empty; reason for change Data Entry Error	Ashley Bell (b) (4)	15 Apr 2021 20:35:04
User entered 'PHYSICIAN DECISION AS listed in AE log SUBJECT EXPERIENCED ANAPHYLAXIS (hives over full body) REACTION TO 1ST DOSE OF STUDY DRUG' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 23:44:02
User entered 'Physician decision as subject experienced anaphylaxis reaction to 1st dose of study drug'	(b) (4), (b) (6)	12 Mar 2021 23:42:40