

US3172265 (Prod: Suncoast Research Group LLC - ERN-PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:05:08

All time stamps listed in this document are displayed in GMT

US3172265

Form: Participant Creation

Data signed: (b) (4) 17 Feb 2021 13:18:06

Generated On: 11 Aug 2021 22:05:08

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Participant ID

US3172265

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

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US3172265

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:18:07

Generated On: 11 Aug 2021 22:05:08

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

Visit date (dd MMM yyyy)	21 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3172265

Folder: Screening

Form: Demographics

Data signed: (b) (4) 17 Feb 2021 13:18:07

Generated On: 11 Aug 2021 22:05:08

Date of Birth (MMM yyyy)	(b) (6) 1985
Age	34
Age Units	YEARS
Age (Derived)	34
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input 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

US3172265

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 17 Feb 2021 13:18:07

Generated On: 11 Aug 2021 22:05:08

Date of Informed Consent (*dd MMM yyyy*) 21 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

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

Was participant enrolled in the study?

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

If No, indicate reason for screen fail

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

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

Was this participant screened previously?

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

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

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 17 Feb 2021 13:18:07

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3172265

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 17 Feb 2021 13:18:07

Generated On: 11 Aug 2021 22:05:08

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Were any significant conditions reported?

Yes ☐

No ☒

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:18:07

Generated On: 11 Aug 2021 22:05:08

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	10:08 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 10:08
Height (xxx.x)	170.7 cm
Weight (xxx.x)	78.3 kg
BMI (xxx.x)	26.87167 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:18:07

Generated On: 11 Aug 2021 22:05:08

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3172265

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 13:18:07

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**Occupational Risk**

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☒ No ☐

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

**Warehouse shipping and fulfillment centers** and jobs (e.g., Amazon facilities) Yes ☐ No ☒

**Transportation and delivery services** (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 13:18:07

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:18:07

Generated On: 11 Aug 2021 22:05:08

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

Visit date (dd MMM yyyy)	21 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 17 Feb 2021 13:18:07

Generated On: 11 Aug 2021 22:05:08

What was the date of randomization? (dd MMM yyyy) 21 AUG 2020

What was the participant's randomization number? 106898

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Feb 2021 13:18:07

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 13:18:07

Generated On: 11 Aug 2021 22:05:08

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)	21 AUG 2020
Time of assessment (00:00-23:59)	10:08 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 10:08
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)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 13:18:07

Generated On: 11 Aug 2021 22:05:08

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)	21 AUG 2020
Time of assessment (00:00-23:59)	12:41 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 12:41
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)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:18:07

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 13:18:07

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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) 21 AUG 2020

What was the treatment time? (00:00-23:59) 12:11 (24 HR)

Treatment Date and Time (derived) 21 AUG 2020 12:11

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:18:07

Generated On: 11 Aug 2021 22:05:08

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

Collection date (dd MMM yyyy)	21 AUG 2020
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Collection time (00:00-23:59)	11:44 (24 HR)
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Collection date and time (derived)	21 AUG 2020 11:44
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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 13:18:07

Generated On: 11 Aug 2021 22:05:08

Collection date (dd MMM yyyy)			21 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:42	21 AUG 2020 11:42
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:18:07

Generated On: 11 Aug 2021 22:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 12:41

PC Open Date & Time

21 AUG 2020 12:31

PC Close Date & Time

21 AUG 2020 15:01

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:05:08

**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 98.0 °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	21 AUG 2020 15:56
PC Open Date & Time	21 AUG 2020 15:56
PC Close Date & Time	22 AUG 2020 11:59

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:05:08

**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

22 AUG 2020 12:20

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59



US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:05:08

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**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

96.0 °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 12:02

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:05:08

**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

98.0 °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 AUG 2020 13:55

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:05:08

**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

96.0 °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

25 AUG 2020 16:12

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:05:08

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

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Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

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PC Time Stamp

26 AUG 2020 12:00

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PC Open Date & Time

26 AUG 2020 12:00

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PC Close Date & Time

27 AUG 2020 11:59

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US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:05:08

**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

96.0 °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

28 AUG 2020 00:00

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 12:37

PC Open Date & Time

21 AUG 2020 12:31

PC Close Date & Time

21 AUG 2020 15:01

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:05:08

**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

21 AUG 2020 15:57

PC Open Date & Time

21 AUG 2020 15:56

PC Close Date & Time

22 AUG 2020 11:59

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:05:08

**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

22 AUG 2020 12:23

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59



US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:05:08

**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

23 AUG 2020 12:03

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:05:08

TIMEPOINT	DAY 4
Please record - <b>PAIN AT INJECTION SITE.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any <b>REDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - <b>UNDERARM GLAND SWELLING OR TENDERNESS.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	24 AUG 2020 13:55
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:05:08

**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

25 AUG 2020 16:12

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:05:08

**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

26 AUG 2020 12:00

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:05:08

**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

28 AUG 2020 00:00

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:05:08

**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 ☐

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:05:08

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

No ☐

Yes ☒

PC Time stamp	21 AUG 2020 12:37
PC Open Date & Time	21 AUG 2020 12:31
PC Close Date & Time	21 AUG 2020 15:01

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:05:08

**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 ☐



US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:05:08

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 15:57
PC Open Date & Time	21 AUG 2020 15:56
PC Close Date & Time	22 AUG 2020 11:59

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:05:08

**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 ☒

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:05:08

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 12:24
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:05:08

		Yes <input type="checkbox"/>
PC Time stamp	23 AUG 2020 12:04	
PC Open Date & Time	23 AUG 2020 12:00	
PC Close Date & Time	24 AUG 2020 11:59	

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

45 of 1506

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:05:08

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 13:55
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:05:08

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 ☒



US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:05:08

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 16:12
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:05:08

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 ☒

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:05:08

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 12:01
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:05:08

**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 ☒

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:05:08

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

US3172265

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:18:06

Generated On: 11 Aug 2021 22:05:08

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*

US3172265

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:18:06

Generated On: 11 Aug 2021 22:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172265

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:18:06

Generated On: 11 Aug 2021 22:05:08

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*



US3172265

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:18:06

Generated On: 11 Aug 2021 22:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172265

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:18:06

Generated On: 11 Aug 2021 22:05:08

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3172265

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:18:06

Generated On: 11 Aug 2021 22:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172265

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:18:23

Generated On: 11 Aug 2021 22:05:08

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

Visit date (dd MMM yyyy)	18 SEP 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 13:18:23

Generated On: 11 Aug 2021 22:05:08

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)	18 SEP 2020
Time of assessment (00:00-23:59)	10:25 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 10:25
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)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 13:18:23

Generated On: 11 Aug 2021 22:05:08

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
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="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
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	

US3172265

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:18:07

Generated On: 11 Aug 2021 22:05:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 SEP 2020

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

US3172265

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 13:18:07

Generated On: 11 Aug 2021 22:05:08

Was study treatment given? Yes ☐  
No ☒

If No, reason not given

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

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

What was the study treatment?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?



US3172265

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:18:07

Generated On: 11 Aug 2021 22:05:08

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 18 SEP 2020

Collection time (00:00-23:59) 11:32 (24 HR)

Collection date and time (derived) 18 SEP 2020 11:32

US3172265

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 13:18:07

Generated On: 11 Aug 2021 22:05:08

Collection date (dd MMM yyyy)			18 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:29	18 SEP 2020 11:29
Nasopharyngeal Swab 2	No		

US3172265

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:18:07

Generated On: 11 Aug 2021 22:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172265

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:18:06

Generated On: 11 Aug 2021 22:05:08

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3172265

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:18:06

Generated On: 11 Aug 2021 22:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172265

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:18:06

Generated On: 11 Aug 2021 22:05:08

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3172265

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:18:06

Generated On: 11 Aug 2021 22:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172265

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:18:06

Generated On: 11 Aug 2021 22:05:08

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3172265

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:18:06

Generated On: 11 Aug 2021 22:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172265

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:18:23

Generated On: 11 Aug 2021 22:05:08

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

Visit date (dd MMM yyyy)	23 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT3
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US3172265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:18:23

Generated On: 11 Aug 2021 22:05:08

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 OCT 2020
Time of assessment (00:00-23:59)	11:55 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 11:55
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)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3172265

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:18:23

Generated On: 11 Aug 2021 22:05:08

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3172265

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:18:23

Generated On: 11 Aug 2021 22:05:08

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

Collection date (dd MMM yyyy)	23 OCT 2020
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Collection time (00:00-23:59)	12:52 (24 HR)
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Collection date and time (derived)	23 OCT 2020 12:52
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US3172265

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:18:23

Generated On: 11 Aug 2021 22:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 OCT 2020 12:11:16

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**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

28 OCT 2020 02:18:01

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59



US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 00:01:30

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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"/>

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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	19 NOV 2020 21:26:09
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 00:01:23
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**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

29 NOV 2020 00:02:12

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 DEC 2020 13:11:36
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 DEC 2020 00:05:39

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59



US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 DEC 2020 02:35:51
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 00:01:47

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**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

05 JAN 2021 19:39:20

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

<b>TIMEPOINT</b>	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 00:12:24
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 JAN 2021 00:01:56
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 00:01:41

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

<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	31 JAN 2021 00:01:44
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**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

07 FEB 2021 00:01:53

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59



US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 FEB 2021 00:06:05

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 00:01:14

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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	28 FEB 2021 05:11:09
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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	07 MAR 2021 00:02:34
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**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

14 MAR 2021 00:02:22

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**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

21 MAR 2021 00:02:33

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**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

28 MAR 2021 00:02:29

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**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

04 APR 2021 00:02:19

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59



US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 APR 2021 00:02:19
Patient Cloud Open Date & Time	11 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**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

18 APR 2021 00:05:11

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**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 09:33:44

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 00:02:27

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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"/>

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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"/>

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59



US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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"/>

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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"/>

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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 <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"/>

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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[Patient Cloud Open Date & Time](#)

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27 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUL 2021 23:59

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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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"/>

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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



US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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="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"/>

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 JUL 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

<a href="#">Patient Cloud Open Date &amp; Time</a>	25 JUL 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 JUL 2021 23:59
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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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"/>

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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 <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"/>

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59



US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2021 23:59
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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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"/>

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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"/>

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59



US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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

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 ☐

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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[Patient Cloud Open Date & Time](#)

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19 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 SEP 2021 23:59

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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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"/>

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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[Patient Cloud Open Date & Time](#)

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26 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 SEP 2021 23:59

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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59



US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 OCT 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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"/>

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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

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 ☐

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 OCT 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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[Patient Cloud Open Date & Time](#)

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31 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 NOV 2021 23:59

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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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"/>

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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[Patient Cloud Open Date & Time](#)

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07 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 NOV 2021 23:59

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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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"/>

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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[Patient Cloud Open Date & Time](#)

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28 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	05 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	09 DEC 2021 23:59
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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	19 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 DEC 2021 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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"/>

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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[Patient Cloud Open Date & Time](#)

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26 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 DEC 2021 23:59

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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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[Patient Cloud Open Date & Time](#)

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02 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 JAN 2022 23:59

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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

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 ☐

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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[Patient Cloud Open Date & Time](#)

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16 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JAN 2022 23:59

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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**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 ☐

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59



US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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"/>

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59



US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**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 ☐

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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[Patient Cloud Open Date & Time](#)

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06 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAR 2022 23:59

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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**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 ☐

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**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 ☐

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59



US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**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 ☐

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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"/>

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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[Patient Cloud Open Date & Time](#)

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10 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 APR 2022 23:59

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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

DAY 607

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

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

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

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

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

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

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

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 APR 2022 23:59



US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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="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"/>

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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[Patient Cloud Open Date & Time](#)

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01 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 MAY 2022 23:59

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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

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 ☐

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**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 ☐

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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

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 ☐

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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[Patient Cloud Open Date & Time](#)

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05 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 JUN 2022 23:59

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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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[Patient Cloud Open Date & Time](#)

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12 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 JUN 2022 23:59

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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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"/>

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

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30 JUN 2022 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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"/>

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

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07 JUL 2022 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

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14 JUL 2022 23:59



US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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[Patient Cloud Open Date & Time](#)

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17 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUL 2022 23:59

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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

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28 JUL 2022 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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"/>

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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

Date and time of submission

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31 JUL 2022 00:01

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04 AUG 2022 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59



US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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[Patient Cloud Open Date & Time](#)

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14 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 AUG 2022 23:59

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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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[Patient Cloud Open Date & Time](#)

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21 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2022 23:59

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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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"/>

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2022 23:59

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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59



US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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"/>

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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[Patient Cloud Open Date & Time](#)

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18 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 SEP 2022 23:59

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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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[Patient Cloud Open Date & Time](#)

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25 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 SEP 2022 23:59

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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**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 ☐

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	02 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	06 OCT 2022 23:59
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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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[Patient Cloud Open Date & Time](#)

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09 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 OCT 2022 23:59

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US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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

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

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 OCT 2022 23:59

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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°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"/>

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

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[Patient Cloud Open Date & Time](#)

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23 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 OCT 2022 23:59

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US3172265

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:05:08

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 05:11:18

US3172265

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:18:07

Generated On: 11 Aug 2021 22:05:08

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3172265

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:18:06

Generated On: 11 Aug 2021 22:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172265

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:18:06

Generated On: 11 Aug 2021 22:05:08

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3172265

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:18:06

Generated On: 11 Aug 2021 22:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172265

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:18:06

Generated On: 11 Aug 2021 22:05:08

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3172265

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:18:06

Generated On: 11 Aug 2021 22:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172265

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:37:47

Generated On: 11 Aug 2021 22:05:08

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3172265

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:37:47

Generated On: 11 Aug 2021 22:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172265

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 16:27:38

Generated On: 11 Aug 2021 22:05:08

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

Visit date (dd MMM yyyy)	25 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3172265

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Apr 2021 16:27:38

Generated On: 11 Aug 2021 22:05:08

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 MAR 2021
Time of assessment (00:00-23:59)	11:33 (24 HR)
Vital Signs Date and Time (derived)	25 MAR 2021 11:33
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)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3172265

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 16:27:38

Generated On: 11 Aug 2021 22:05:08

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3172265

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Apr 2021 16:27:38

Generated On: 11 Aug 2021 22:05:08

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

Collection date (dd MMM yyyy)	25 MAR 2021
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Collection time (00:00-23:59)	13:01 (24 HR)
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Collection date and time (derived)	25 MAR 2021 13:01
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US3172265

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:27:38

Generated On: 11 Aug 2021 22:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172265

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:27:38

Generated On: 11 Aug 2021 22:05:08

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 APR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3172265

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:27:38

Generated On: 11 Aug 2021 22:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172265

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

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*

**US3172265**

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

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:08**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



US3172265

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:05:08

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

**US3172265**

**Folder: Covid-19 Assessment (1)**

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

**Generated On: 11 Aug 2021 22:05:08**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 03 Mar 2021 13:56:38

Generated On: 11 Aug 2021 22:05:08

Was this visit performed? Yes ☒  
No ☐

Visit date (dd MMM yyyy) 23 FEB 2021

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

Folder OID UNBLND\_DECIDE

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 16:27:38

Generated On: 11 Aug 2021 22:05:08

Date of updated informed consent ( <i>dd MMM yyyy</i> )	06 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> )	23 FEB 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	1

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 09 Mar 2021 14:42:08

Generated On: 11 Aug 2021 22:05:08

Height	ND - Not Done
Weight	077.8 kg
BMI (xxx.x)	

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Mar 2021 14:42:08

Generated On: 11 Aug 2021 22:05:08

Height	ND - Not Done
Weight	077.8 kg
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)	23 FEB 2021
Time of assessment (00:00-23:59)	10:36 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 10:36
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)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Mar 2021 14:42:08

Generated On: 11 Aug 2021 22:05:08

Height	ND - Not Done
Weight	077.8 kg
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)	23 FEB 2021
Time of assessment (00:00-23:59)	12:50 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 12:50
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Mar 2021 13:56:38

Generated On: 11 Aug 2021 22:05:08

Was the physical examination performed?

Yes ☒  
No ☐

Date of examination (dd MMM yyyy)

23 FEB 2021

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



US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 03 Mar 2021 13:56:38

Generated On: 11 Aug 2021 22:05:08

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 23 FEB 2021

What was the treatment time? (00:00-23:59) 12:20 (24 HR)

Treatment Date and Time (derived) 23 FEB 2021 12:20

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

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Mar 2021 13:56:38

Generated On: 11 Aug 2021 22:05:08

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

Collection date (dd MMM yyyy)	23 FEB 2021
-------------------------------	-------------

Collection time (00:00-23:59)	11:36 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	23 FEB 2021 11:36
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US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 03 Mar 2021 13:56:38

Generated On: 11 Aug 2021 22:05:08

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

Collection date (dd MMM yyyy)	23 FEB 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	11:38
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Collection Date and Time (derived)	23 FEB 2021 11:38
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US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 13:56:38

Generated On: 11 Aug 2021 22:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172265

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:27:38

Generated On: 11 Aug 2021 22:05:08

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

MISSED

If Contact Not Made, please provide Comments

US3172265

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:27:38

Generated On: 11 Aug 2021 22:05:08

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3172265

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 16:27:38

Generated On: 11 Aug 2021 22:05:08

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

Visit date (dd MMM yyyy)	25 MAR 2021
--------------------------	-------------

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

Folder OID	OLD29
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US3172265

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Apr 2021 16:27:38

Generated On: 11 Aug 2021 22:05:08

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 MAR 2021
Time of assessment (00:00-23:59)	11:33 (24 HR)
Vital Signs Date and Time (derived)	25 MAR 2021 11:33
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)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Apr 2021 16:27:38

Generated On: 11 Aug 2021 22:05:08

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)	25 MAR 2021
Time of assessment (00:00-23:59)	11:33 (24 HR)
Vital Signs Date and Time (derived)	25 MAR 2021 11:33
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)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Apr 2021 16:27:38

Generated On: 11 Aug 2021 22:05:08

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

US3172265

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 16:27:38

Generated On: 11 Aug 2021 22:05:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 MAR 2021

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

US3172265

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 22 Apr 2021 16:27:31

Generated On: 11 Aug 2021 22:05:08

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 SUBJECT FIRST MRNA DOSE WAS 21AUG2020 AND SUBJECT SECOND DOSE WAS TAKEN 23FEB2020.

What was the study treatment? \_\_\_\_\_

What was the treatment date? (dd MMM yyyy) \_\_\_\_\_

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

Treatment Date and Time (derived) \_\_\_\_\_

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

What was the frequency of the study treatment dosing? \_\_\_\_\_

What was the route of administration for the study treatment? \_\_\_\_\_

US3172265

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Apr 2021 16:27:31

Generated On: 11 Aug 2021 22:05:08

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 25 MAR 2021

Collection time (00:00-23:59) 13:01 (24 HR)

Collection date and time (derived) 25 MAR 2021 13:01

US3172265

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:27:31

Generated On: 11 Aug 2021 22:05:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3172265**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:08**

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*

**US3172265**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:08**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



US3172265

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 17 Feb 2021 13:18:06

Generated On: 11 Aug 2021 22:05:08

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3172265

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 17 Feb 2021 13:18:06

Generated On: 11 Aug 2021 22:05:08

AEID	
Adverse event	SKIN RASH (CONSISTENT WITH HIVES) (ARMS, LEGS, CHEST, AND BACK)
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	22 AUG 2020
Start time (00:00-23:59)	23:00 (24 HR)
AE start date and time (derived)	22 AUG 2020 23:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 AUG 2020
End time (00:00-23:59)	05:00 (24 HR)
AE End Date and Time (derived)	25 AUG 2020 05:00
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"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3172265

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 17 Feb 2021 13:18:06

Generated On: 11 Aug 2021 22:05:08

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input 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 Withdrawn <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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)	

US3172265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 17 Feb 2021 13:18:06

Generated On: 11 Aug 2021 22:05:08

---

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

---

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

---

US3172265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 17 Feb 2021 13:18:06

Generated On: 11 Aug 2021 22:05:08

Name of Medication LORATTADINE

Prophylaxis Yes ☐  
No ☒

Indication SKIN RASH (HIVES)

Dose per administration 10

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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EAB) (1725)

US3172265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 17 Feb 2021 13:18:06

Generated On: 11 Aug 2021 22:05:08

	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)	24 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 24 AUG 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3172265

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 17 Feb 2021 13:18:06

Generated On: 11 Aug 2021 22:05:08

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3172265

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 17 Feb 2021 13:18:06

Generated On: 11 Aug 2021 22:05:08

Date of dosing discontinuation (dd MMM yyyy) 24 AUG 2020

Primary reason for dosing discontinuation

AE (specify)	<input checked="" type="radio"/>
SAE (specify)	<input type="radio"/>
Death	<input type="radio"/>
Lost To Follow-up	<input type="radio"/>
Physician decision (specify)	<input type="radio"/>
Pregnancy	<input type="radio"/>
Protocol deviation (specify)	<input type="radio"/>
Study Terminated By Sponsor	<input type="radio"/>
Withdrawal of consent by participant (specify)	<input type="radio"/>
Due to SARS-COV-2	<input type="radio"/>
Other	<input type="radio"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify A/E #1.



US3172265

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:05:08

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

US3172265 (Prod: Suncoast Research Group LLC - ERN-PPDS)

**US3172265**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 22:05:08**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'US3172265'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 15:39:35

US3172265

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:05:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:19:55

US3172265

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:05:08

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '21 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 15:39:36

US3172265

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:05:08

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:19:55

US3172265

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:05:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User entered 'SCRN'	System	21 Aug 2020 16:19:55

US3172265

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:08

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered (b) (6) 1985'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 15:39:37



US3172265

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:08

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User closed query 'Age does not fit Date of Birth.' (Site from System).	System	21 Aug 2020 16:20:59
User entered '34' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:59
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	21 Aug 2020 16:20:38
User entered '35'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:38

**US3172265**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:05:08**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User entered 'YEARS'	System	21 Aug 2020 16:20:38

US3172265

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:08

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User entered '34'	System	21 Aug 2020 16:18:38

US3172265

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:08

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Male (M)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:38

US3172265

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:08

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:38

US3172265

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:08

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:38

US3172265

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:08

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:38

US3172265

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:08

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:38



US3172265

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:08

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:38

US3172265

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:08

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:38

US3172265

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:08

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:38

US3172265

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:08

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:38

US3172265

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:08

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:38

US3172265

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:05:08

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:38

US3172265

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:08

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '21 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:18:38

US3172265

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:08

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User entered 'Aug 2020'	System	21 Aug 2020 16:18:38



US3172265

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:08

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User entered '2020'	System	21 Aug 2020 16:18:38

US3172265

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:08

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Amendment 1 (1)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:13:09
User entered 'Amendment 2 (2)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:18:38

US3172265

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:08

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:18:38

US3172265

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:08

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:18:38

US3172265

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:08

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:18:38

US3172265

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:08

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:18:38

US3172265

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:08

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 15:39:36

US3172265

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:05:08

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User entered 'I'	System	21 Aug 2020 16:18:43



US3172265

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:05:08

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:18:43

US3172265

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:05:08

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:25:15

US3172265

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:21:25

US3172265

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '21 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:21:25

US3172265

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '10:08'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:21:25

US3172265

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User entered '21 Aug 2020 10:08'	System	21 Aug 2020 16:21:25

US3172265

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '170.7' cm	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:21:25
DataPoint set to visible.	System	21 Aug 2020 16:18:43

US3172265

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '78.3' kg	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:21:25
DataPoint set to visible.	System	21 Aug 2020 16:18:43



US3172265

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
Amendment Manager: User entered '26.87167'	System	17 Sep 2020 00:18:13
User entered '26.9'	System	21 Aug 2020 16:21:25
DataPoint set to visible.	System	21 Aug 2020 16:18:43

US3172265

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User entered 'kg/m2'	System	21 Aug 2020 16:21:25
DataPoint set to visible.	System	21 Aug 2020 16:18:43

US3172265

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:21:25

US3172265

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:21:25

US3172265

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:21:25

US3172265

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:21:25

**US3172265**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:08**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User entered 'bpm'	System	21 Aug 2020 16:21:25

US3172265

Folder: Screening

Form: Vital Signs

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[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:21:25



US3172265

Folder: Screening

Form: Vital Signs

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[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User entered 'breaths/min'	System	21 Aug 2020 16:21:25

US3172265

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:21:25

US3172265

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User entered 'mmHg'	System	21 Aug 2020 16:21:25

US3172265

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:21:25

US3172265

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User entered 'mmHg'	System	21 Aug 2020 16:21:25

US3172265

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12

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Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12

US3172265

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 14:30:19
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:22:16



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Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 14:30:19
User entered '21 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:22:16

US3172265

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:08

**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 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:22

US3172265

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:08

**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 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:08

**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 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:08

**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 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:22

US3172265

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:08

[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 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:08

[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 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:08

**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 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:22



US3172265

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:08

**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 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:22

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Folder: Screening

Form: Risk of Exposure

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[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 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:22

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Folder: Screening

Form: Risk of Exposure

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**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 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:22

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**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 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:22

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:22

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Folder: Screening

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:22

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:08

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:22



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**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 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:22

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**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 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:22

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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 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:22

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Folder: Screening

Form: Risk of Exposure

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[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:08

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:05:08

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:20:22

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:05:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:23:54

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:05:08

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '21 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:23:54



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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:05:08

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:23:54

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:05:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered 'VISIT1'	System	21 Aug 2020 16:23:54

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '21 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 15:39:42

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:08

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '106898'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 15:39:42

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:08

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 15:39:42

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:08

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:04

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:08

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:04

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:08

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:04



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Folder: Visit 1 Day 1

Form: Randomization

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Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:04

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:05:08

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:08

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:08

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:08

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:08

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User accepted default value 'Pre-Dose (PREDOSE)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:37



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '21 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:18:07
	(b) (4)	
User entered '10:08'	Mariete Rendon (b) (4)	21 Aug 2020 16:24:37
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered '21 Aug 2020 10:08'	System	21 Aug 2020 16:24:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '36.7' C	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '69'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered 'bpm'	System	21 Aug 2020 16:24:37



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '16'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered 'breaths/min'	System	21 Aug 2020 16:24:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '135'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered 'mmHg'	System	21 Aug 2020 16:24:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '90'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered 'mmHg'	System	21 Aug 2020 16:24:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

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[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:08

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:37



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User accepted default value 'Post-Dose (POSTDOSE)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 18:04:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 18:04:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 18:04:15
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 16:24:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '21 Aug 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 18:04:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '12:41' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 18:04:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered '21 Aug 2020 12:41'	System	21 Aug 2020 18:04:15
User entered empty.	System	21 Aug 2020 16:24:37

US3172265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '36.8' C reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 18:04:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:37

US3172265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Oral (Oral)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 18:04:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:37

US3172265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:37



US3172265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '62' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 18:04:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:37

US3172265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered 'bpm'	System	21 Aug 2020 18:04:15
User entered empty.	System	21 Aug 2020 16:24:37

US3172265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '14' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 18:04:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:37

US3172265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered 'breaths/min'	System	21 Aug 2020 18:04:15
User entered empty.	System	21 Aug 2020 16:24:37

US3172265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '131' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 18:04:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:37

US3172265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered 'mmHg'	System	21 Aug 2020 18:04:15
User entered empty.	System	21 Aug 2020 16:24:37

US3172265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '88' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 18:04:15
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:37

US3172265

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered 'mmHg'	System	21 Aug 2020 18:04:15
User entered empty.	System	21 Aug 2020 16:24:37



US3172265

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 14:30:33
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:24:48

US3172265

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:18:07
	(b) (4)	
User entered '21 Aug 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	05 Oct 2020 14:30:33
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	21 Aug 2020 16:24:48
	(b) (4)	

US3172265

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:19:01

US3172265

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:19:01

US3172265

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:19:01

US3172265

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered 'MRNA-1273 OR PLACEBO'	System	21 Aug 2020 16:19:01

US3172265

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:18:07
	(b) (4)	
User entered '21 Aug 2020'	Mariete Rendon (b) (4)	21 Aug 2020 16:19:01
	(b) (4)	

US3172265

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '12:11'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:19:01



US3172265

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered '21 Aug 2020 12:11'	System	21 Aug 2020 16:19:01

US3172265

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Left Arm (LEFT ARM)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:19:01

US3172265

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered 'ONCE'	System	21 Aug 2020 16:19:01

US3172265

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered 'INTRAMUSCULAR'	System	21 Aug 2020 16:19:01

US3172265

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:25:32

US3172265

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '21 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:25:32

US3172265

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '11:44'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:25:32

US3172265

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:08

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered '21 Aug 2020 11:44'	System	21 Aug 2020 16:25:32



US3172265

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:05:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '21 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:25:46

US3172265

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:25:46

US3172265

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:25:46

US3172265

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '11:42'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:25:46

**US3172265**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:05:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered '21 Aug 2020 11:42'	System	21 Aug 2020 16:25:46

US3172265

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:25:46

US3172265

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 14:56:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:25:46

US3172265

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 14:56:07
User entered '11:42'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 16:25:46



US3172265

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:08

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered empty.	System	17 Sep 2020 14:56:07
User entered '21 Aug 2020 11:42'	System	21 Aug 2020 16:25:46

US3172265

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Aug 2020 18:04:22

US3172265

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered 'I'	System	21 Aug 2020 18:04:22

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:05:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T12:41:37', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '5a2b28b2-d979-4ecf-b9e8-535696ceeffb'	System	21 Aug 2020 16:43:17
User entered 'Yes (Y)'	System	21 Aug 2020 16:43:17

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:05:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T12:41:41', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '5a2b28b2-d979-4ecf-b9e8-535696ceeffb'	System	21 Aug 2020 16:43:17
User entered '98.2'	System	21 Aug 2020 16:43:17

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T12:41:44', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '5a2b28b2-d979-4ecf-b9e8-535696ceeffb'	System	21 Aug 2020 16:43:17
User entered 'No (N)'	System	21 Aug 2020 16:43:17

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T12:41:46', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '5a2b28b2-d979-4ecf-b9e8-535696ceeffb'	System	21 Aug 2020 16:43:17
User entered '21 Aug 2020 12:41'	System	21 Aug 2020 16:43:17



US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '21 Aug 2020 12:31'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '21 Aug 2020 15:01'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:05:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T15:56:35', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '8e7302ee-a4a0-4a0f-b499-e52b4eae9723'	System	21 Aug 2020 19:58:06
User entered 'Yes (Y)'	System	21 Aug 2020 19:58:06

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:05:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T15:56:44', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '8e7302ee-a4a0-4a0f-b499-e52b4eae9723'	System	21 Aug 2020 19:58:06
User entered '98.0'	System	21 Aug 2020 19:58:06

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T15:56:48', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '8e7302ee-a4a0-4a0f-b499-e52b4eae9723'	System	21 Aug 2020 19:58:06
User entered 'No (N)'	System	21 Aug 2020 19:58:06

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T15:56:50', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '8e7302ee-a4a0-4a0f-b499-e52b4eae9723'	System	21 Aug 2020 19:58:06
User entered '21 Aug 2020 15:56'	System	21 Aug 2020 19:58:06

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '21 Aug 2020 15:56'	System	21 Aug 2020 16:19:01



US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered 'Day 2'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:05:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-22T12:19:51', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'bb1a95c5-163c-4a8f-b897-f034d9ec70e0'	System	22 Aug 2020 16:21:16
User entered 'Yes (Y)'	System	22 Aug 2020 16:21:16

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:05:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-22T12:19:56', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'bb1a95c5-163c-4a8f-b897-f034d9ec70e0'	System	22 Aug 2020 16:21:16
User entered '98.0'	System	22 Aug 2020 16:21:16

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-22T12:20:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'bb1a95c5-163c-4a8f-b897-f034d9ec70e0'	System	22 Aug 2020 16:21:16
User entered 'No (N)'	System	22 Aug 2020 16:21:16

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-22T12:20:02', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'bb1a95c5-163c-4a8f-b897-f034d9ec70e0'	System	22 Aug 2020 16:21:16
User entered '22 Aug 2020 12:20'	System	22 Aug 2020 16:21:16

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 16:19:01



US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered 'Day 3'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:05:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-23T12:02:38', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'd1baaf92-bc3a-43be-a7c1-ed06e656fea6'	System	23 Aug 2020 16:04:09
User entered 'Yes (Y)'	System	23 Aug 2020 16:04:09

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:05:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-23T12:02:44', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'd1baaf92-bc3a-43be-a7c1-ed06e656fea6'	System	23 Aug 2020 16:04:09
User entered '96.0'	System	23 Aug 2020 16:04:09

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-23T12:02:49', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'd1baaf92-bc3a-43be-a7c1-ed06e656fea6'	System	23 Aug 2020 16:04:09
User entered 'No (N)'	System	23 Aug 2020 16:04:09

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-23T12:02:52', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'd1baaf92-bc3a-43be-a7c1-ed06e656fea6'	System	23 Aug 2020 16:04:09
User entered '23 Aug 2020 12:02'	System	23 Aug 2020 16:04:09

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered 'Day 4'	System	21 Aug 2020 16:19:01



US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:05:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-24T13:55:39', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '884cb2ee-204f-4303-aebd-c03fa27a2f7c'	System	24 Aug 2020 17:57:02
User entered 'Yes (Y)'	System	24 Aug 2020 17:57:02

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:05:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-24T13:55:42', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '884cb2ee-204f-4303-aebd-c03fa27a2f7c'	System	24 Aug 2020 17:57:02
User entered '98.0'	System	24 Aug 2020 17:57:02

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-24T13:55:46', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '884cb2ee-204f-4303-aebd-c03fa27a2f7c'	System	24 Aug 2020 17:57:02
User entered 'No (N)'	System	24 Aug 2020 17:57:02

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-24T13:55:48', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '884cb2ee-204f-4303-aebd-c03fa27a2f7c'	System	24 Aug 2020 17:57:02
User entered '24 Aug 2020 13:55'	System	24 Aug 2020 17:57:02

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered 'Day 5'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:05:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-25T16:11:57', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '943ee1ea-68de-4204-868c-7d85caa45272'	System	25 Aug 2020 20:13:47
User entered 'Yes (Y)'	System	25 Aug 2020 20:13:47



US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:05:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-25T16:11:59', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '943ee1ea-68de-4204-868c-7d85caa45272'	System	25 Aug 2020 20:13:47
User entered '96.0'	System	25 Aug 2020 20:13:47

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-25T16:12:02', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '943ee1ea-68de-4204-868c-7d85caa45272'	System	25 Aug 2020 20:13:47
User entered 'No (N)'	System	25 Aug 2020 20:13:47

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-25T16:12:03', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '943ee1ea-68de-4204-868c-7d85caa45272'	System	25 Aug 2020 20:13:47
User entered '25 Aug 2020 16:12'	System	25 Aug 2020 20:13:47

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered 'Day 6'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:05:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-26T12:00:34', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '36997985-30f4-4121-8e58-694cb0cba656'	System	26 Aug 2020 16:02:32
User entered 'Yes (Y)'	System	26 Aug 2020 16:02:32

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:05:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-26T12:00:40', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '36997985-30f4-4121-8e58-694cb0cba656'	System	26 Aug 2020 16:02:32
User entered '98.0'	System	26 Aug 2020 16:02:32



US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-26T12:00:42', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '36997985-30f4-4121-8e58-694cb0cba656'	System	26 Aug 2020 16:02:32
User entered 'No (N)'	System	26 Aug 2020 16:02:32

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-26T12:00:44', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '36997985-30f4-4121-8e58-694cb0cba656'	System	26 Aug 2020 16:02:32
User entered '26 Aug 2020 12:00'	System	26 Aug 2020 16:02:32

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered 'Day 7'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:05:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-28T00:00:15', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '036c4437-d38e-4aaa-aa9a-6f60f898b9dd'	System	28 Aug 2020 04:01:40
User entered 'Yes (Y)'	System	28 Aug 2020 04:01:40

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:05:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-28T00:00:19', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '036c4437-d38e-4aaa-aa9a-6f60f898b9dd'	System	28 Aug 2020 04:01:40
User entered '96.0'	System	28 Aug 2020 04:01:40

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-28T00:00:22', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '036c4437-d38e-4aaa-aa9a-6f60f898b9dd'	System	28 Aug 2020 04:01:40
User entered 'No (N)'	System	28 Aug 2020 04:01:40



US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-28T00:00:24', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '036c4437-d38e-4aaa-aa9a-6f60f898b9dd'	System	28 Aug 2020 04:01:40
User entered '28 Aug 2020 00:00'	System	28 Aug 2020 04:01:40

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T12:36:52', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '916bd01f-109e-4994-808a-8d9b63aa1081'	System	21 Aug 2020 16:38:29
User entered 'None (1)'	System	21 Aug 2020 16:38:29

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T12:36:56', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '916bd01f-109e-4994-808a-8d9b63aa1081'	System	21 Aug 2020 16:38:29
User entered 'No (N)'	System	21 Aug 2020 16:38:29

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T12:37:04', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '916bd01f-109e-4994-808a-8d9b63aa1081'	System	21 Aug 2020 16:38:29
User entered 'No (N)'	System	21 Aug 2020 16:38:29

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T12:37:07', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '916bd01f-109e-4994-808a-8d9b63aa1081'	System	21 Aug 2020 16:38:29
User entered 'None (1)'	System	21 Aug 2020 16:38:29



US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T12:37:13', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '916bd01f-109e-4994-808a-8d9b63aa1081'	System	21 Aug 2020 16:38:29
User entered '21 Aug 2020 12:37'	System	21 Aug 2020 16:38:29

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '21 Aug 2020 12:31'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '21 Aug 2020 15:01'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T15:56:56', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '98cb741f-df32-4bb6-9eb5-2ddab71da48d'	System	21 Aug 2020 19:58:25
User entered 'None (1)'	System	21 Aug 2020 19:58:25

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T15:57:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '98cb741f-df32-4bb6-9eb5-2ddab71da48d'	System	21 Aug 2020 19:58:25
User entered 'No (N)'	System	21 Aug 2020 19:58:25

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T15:57:03', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '98cb741f-df32-4bb6-9eb5-2ddab71da48d'	System	21 Aug 2020 19:58:25
User entered 'No (N)'	System	21 Aug 2020 19:58:25

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T15:57:08', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '98cb741f-df32-4bb6-9eb5-2ddab71da48d'	System	21 Aug 2020 19:58:25
User entered 'None (1)'	System	21 Aug 2020 19:58:25



**US3172265**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:05:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T15:57:10', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '98cb741f-df32-4bb6-9eb5-2ddab71da48d'	System	21 Aug 2020 19:58:25
User entered '21 Aug 2020 15:57'	System	21 Aug 2020 19:58:25

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '21 Aug 2020 15:56'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered 'Day 2'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-22T12:23:43', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '58dec2c1-99e1-49d2-9ffa-a474ec555caa'	System	22 Aug 2020 16:25:14
User entered 'None (1)'	System	22 Aug 2020 16:25:14

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:05:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-22T12:23:46', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '58dec2c1-99e1-49d2-9ffa-a474ec555caa'	System	22 Aug 2020 16:25:14
User entered 'No (N)'	System	22 Aug 2020 16:25:14

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-22T12:23:51', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '58dec2c1-99e1-49d2-9ffa-a474ec555caa'	System	22 Aug 2020 16:25:14
User entered 'No (N)'	System	22 Aug 2020 16:25:14

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-22T12:23:55', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '58dec2c1-99e1-49d2-9ffa-a474ec555caa'	System	22 Aug 2020 16:25:14
User entered 'None (1)'	System	22 Aug 2020 16:25:14



**US3172265**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:05:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-22T12:23:57', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '58dec2c1-99e1-49d2-9ffa-a474ec555caa'	System	22 Aug 2020 16:25:14
User entered '22 Aug 2020 12:23'	System	22 Aug 2020 16:25:14

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered 'Day 3'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-23T12:03:03', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '1c70cdb2-d2dc-4615-851f-c8e313ad94c7'	System	23 Aug 2020 16:04:33
User entered 'None (1)'	System	23 Aug 2020 16:04:33

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:05:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-23T12:03:07', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '1c70cdb2-d2dc-4615-851f-c8e313ad94c7'	System	23 Aug 2020 16:04:33
User entered 'No (N)'	System	23 Aug 2020 16:04:33

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-23T12:03:10', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '1c70cdb2-d2dc-4615-851f-c8e313ad94c7'	System	23 Aug 2020 16:04:33
User entered 'No (N)'	System	23 Aug 2020 16:04:33

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-23T12:03:14', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '1c70cdb2-d2dc-4615-851f-c8e313ad94c7'	System	23 Aug 2020 16:04:33
User entered 'None (1)'	System	23 Aug 2020 16:04:33



US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-23T12:03:16', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '1c70cdb2-d2dc-4615-851f-c8e313ad94c7'	System	23 Aug 2020 16:04:33
User entered '23 Aug 2020 12:03'	System	23 Aug 2020 16:04:33

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered 'Day 4'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-24T13:54:03', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '2dc9c009-87d1-4e89-a395-6f81391f11ad'	System	24 Aug 2020 17:56:23
User entered 'None (1)'	System	24 Aug 2020 17:56:23

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:05:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-24T13:54:49', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '2dc9c009-87d1-4e89-a395-6f81391f11ad'	System	24 Aug 2020 17:56:23
User entered 'No (N)'	System	24 Aug 2020 17:56:23

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-24T13:54:56', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '2dc9c009-87d1-4e89-a395-6f81391f11ad'	System	24 Aug 2020 17:56:23
User entered 'No (N)'	System	24 Aug 2020 17:56:23

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-24T13:55:01', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '2dc9c009-87d1-4e89-a395-6f81391f11ad'	System	24 Aug 2020 17:56:23
User entered 'None (1)'	System	24 Aug 2020 17:56:23



US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-24T13:55:08', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '2dc9c009-87d1-4e89-a395-6f81391f11ad'	System	24 Aug 2020 17:56:23
User entered '24 Aug 2020 13:55'	System	24 Aug 2020 17:56:23

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered 'Day 5'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-25T16:12:06', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '70590371-8711-4cd4-bb01-a9d676c1966b'	System	25 Aug 2020 20:13:48
User entered 'None (1)'	System	25 Aug 2020 20:13:48

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:05:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-25T16:12:08', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '70590371-8711-4cd4-bb01-a9d676c1966b'	System	25 Aug 2020 20:13:48
User entered 'No (N)'	System	25 Aug 2020 20:13:48

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-25T16:12:11', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '70590371-8711-4cd4-bb01-a9d676c1966b'	System	25 Aug 2020 20:13:48
User entered 'No (N)'	System	25 Aug 2020 20:13:48

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-25T16:12:13', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '70590371-8711-4cd4-bb01-a9d676c1966b'	System	25 Aug 2020 20:13:48
User entered 'None (1)'	System	25 Aug 2020 20:13:48



US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-25T16:12:15', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '70590371-8711-4cd4-bb01-a9d676c1966b'	System	25 Aug 2020 20:13:48
User entered '25 Aug 2020 16:12'	System	25 Aug 2020 20:13:48

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered 'Day 6'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-26T12:00:47', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '69754d14-63c5-4042-bb12-9a16bd6c3598'	System	26 Aug 2020 16:02:43
User entered 'None (1)'	System	26 Aug 2020 16:02:43

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:05:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-26T12:00:49', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '69754d14-63c5-4042-bb12-9a16bd6c3598'	System	26 Aug 2020 16:02:43
User entered 'No (N)'	System	26 Aug 2020 16:02:43

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-26T12:00:51', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '69754d14-63c5-4042-bb12-9a16bd6c3598'	System	26 Aug 2020 16:02:43
User entered 'No (N)'	System	26 Aug 2020 16:02:43

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-26T12:00:52', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '69754d14-63c5-4042-bb12-9a16bd6c3598'	System	26 Aug 2020 16:02:43
User entered 'None (1)'	System	26 Aug 2020 16:02:43



US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:05:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-26T12:00:54', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '69754d14-63c5-4042-bb12-9a16bd6c3598'	System	26 Aug 2020 16:02:43
User entered '26 Aug 2020 12:00'	System	26 Aug 2020 16:02:43

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered 'Day 7'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-28T00:00:03', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '58b56efc-2d44-4d34-81a8-ce5a643b3c30'	System	28 Aug 2020 04:01:24
User entered 'None (1)'	System	28 Aug 2020 04:01:24

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:05:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-28T00:00:05', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '58b56efc-2d44-4d34-81a8-ce5a643b3c30'	System	28 Aug 2020 04:01:24
User entered 'No (N)'	System	28 Aug 2020 04:01:24

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-28T00:00:06', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '58b56efc-2d44-4d34-81a8-ce5a643b3c30'	System	28 Aug 2020 04:01:24
User entered 'No (N)'	System	28 Aug 2020 04:01:24

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:05:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-28T00:00:08', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '58b56efc-2d44-4d34-81a8-ce5a643b3c30'	System	28 Aug 2020 04:01:24
User entered 'None (1)'	System	28 Aug 2020 04:01:24



**US3172265**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:05:08**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-28T00:00:10', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '58b56efc-2d44-4d34-81a8-ce5a643b3c30'	System	28 Aug 2020 04:01:24
User entered '28 Aug 2020 00:00'	System	28 Aug 2020 04:01:24

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 16:19:01

**US3172265**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:05:08**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T12:37:39', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '9f13e4d6-5a4b-4d02-8a06-60d29ea18280'	System	21 Aug 2020 16:39:10
User entered 'None (0)'	System	21 Aug 2020 16:39:10

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:05:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T12:37:41', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '9f13e4d6-5a4b-4d02-8a06-60d29ea18280'	System	21 Aug 2020 16:39:10
User entered 'None (0)'	System	21 Aug 2020 16:39:10

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:05:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T12:37:42', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '9f13e4d6-5a4b-4d02-8a06-60d29ea18280'	System	21 Aug 2020 16:39:10
User entered 'None (0)'	System	21 Aug 2020 16:39:10

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:05:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T12:37:43', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '9f13e4d6-5a4b-4d02-8a06-60d29ea18280'	System	21 Aug 2020 16:39:10
User entered 'None (0)'	System	21 Aug 2020 16:39:10



US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:05:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T12:37:45', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '9f13e4d6-5a4b-4d02-8a06-60d29ea18280'	System	21 Aug 2020 16:39:10
User entered 'None (0)'	System	21 Aug 2020 16:39:10

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:05:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T12:37:46', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '9f13e4d6-5a4b-4d02-8a06-60d29ea18280'	System	21 Aug 2020 16:39:10
User entered 'None (0)'	System	21 Aug 2020 16:39:10

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T12:37:48', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '9f13e4d6-5a4b-4d02-8a06-60d29ea18280'	System	21 Aug 2020 16:39:10
User entered 'Yes (Y)'	System	21 Aug 2020 16:39:10

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:05:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T12:37:51', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '9f13e4d6-5a4b-4d02-8a06-60d29ea18280'	System	21 Aug 2020 16:39:10
User entered '21 Aug 2020 12:37'	System	21 Aug 2020 16:39:10

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '21 Aug 2020 12:31'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '21 Aug 2020 15:01'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:05:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T15:57:15', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'd3cea8b3-369e-4e31-9bde-5d8710d186ce'	System	21 Aug 2020 19:58:52
User entered 'None (0)'	System	21 Aug 2020 19:58:52



US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:05:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T15:57:17', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'd3cea8b3-369e-4e31-9bde-5d8710d186ce'	System	21 Aug 2020 19:58:52
User entered 'None (0)'	System	21 Aug 2020 19:58:52

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:05:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T15:57:24', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'd3cea8b3-369e-4e31-9bde-5d8710d186ce'	System	21 Aug 2020 19:58:52
User entered 'None (0)'	System	21 Aug 2020 19:58:52

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:05:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T15:57:28', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'd3cea8b3-369e-4e31-9bde-5d8710d186ce'	System	21 Aug 2020 19:58:52
User entered 'None (0)'	System	21 Aug 2020 19:58:52

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:05:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T15:57:30', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'd3cea8b3-369e-4e31-9bde-5d8710d186ce'	System	21 Aug 2020 19:58:52
User entered 'None (0)'	System	21 Aug 2020 19:58:52

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:05:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T15:57:32', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'd3cea8b3-369e-4e31-9bde-5d8710d186ce'	System	21 Aug 2020 19:58:52
User entered 'None (0)'	System	21 Aug 2020 19:58:52

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T15:57:36', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'd3cea8b3-369e-4e31-9bde-5d8710d186ce'	System	21 Aug 2020 19:58:52
User entered 'No (N)'	System	21 Aug 2020 19:58:52

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:05:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-21T15:57:38', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'd3cea8b3-369e-4e31-9bde-5d8710d186ce'	System	21 Aug 2020 19:58:52
User entered '21 Aug 2020 15:57'	System	21 Aug 2020 19:58:52

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '21 Aug 2020 15:56'	System	21 Aug 2020 16:19:01



US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered 'Day 2'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:05:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-22T12:24:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'e18e6f31-ef80-4930-8b24-d815e86c4eb2'	System	22 Aug 2020 16:25:30
User entered 'None (0)'	System	22 Aug 2020 16:25:30

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:05:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-22T12:24:04', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'e18e6f31-ef80-4930-8b24-d815e86c4eb2'	System	22 Aug 2020 16:25:30
User entered 'None (0)'	System	22 Aug 2020 16:25:30

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:05:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-22T12:24:06', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'e18e6f31-ef80-4930-8b24-d815e86c4eb2'	System	22 Aug 2020 16:25:30
User entered 'None (0)'	System	22 Aug 2020 16:25:30

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:05:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-22T12:24:08', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'e18e6f31-ef80-4930-8b24-d815e86c4eb2'	System	22 Aug 2020 16:25:30
User entered 'None (0)'	System	22 Aug 2020 16:25:30

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:05:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-22T12:24:09', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'e18e6f31-ef80-4930-8b24-d815e86c4eb2'	System	22 Aug 2020 16:25:30
User entered 'None (0)'	System	22 Aug 2020 16:25:30

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:05:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-22T12:24:11', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'e18e6f31-ef80-4930-8b24-d815e86c4eb2'	System	22 Aug 2020 16:25:30
User entered 'None (0)'	System	22 Aug 2020 16:25:30



US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-22T12:24:15', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'e18e6f31-ef80-4930-8b24-d815e86c4eb2'	System	22 Aug 2020 16:25:30
User entered 'No (N)'	System	22 Aug 2020 16:25:30

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:05:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-22T12:24:17', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'e18e6f31-ef80-4930-8b24-d815e86c4eb2'	System	22 Aug 2020 16:25:30
User entered '22 Aug 2020 12:24'	System	22 Aug 2020 16:25:30

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered 'Day 3'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:05:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-23T12:03:25', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'd871307c-a48e-4bd8-9459-49ca5c1e88c5'	System	23 Aug 2020 16:05:48
User entered 'None (0)'	System	23 Aug 2020 16:05:48

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:05:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-23T12:03:56', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'd871307c-a48e-4bd8-9459-49ca5c1e88c5'	System	23 Aug 2020 16:05:48
User entered 'None (0)'	System	23 Aug 2020 16:05:48

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:05:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-23T12:04:01', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'd871307c-a48e-4bd8-9459-49ca5c1e88c5'	System	23 Aug 2020 16:05:48
User entered 'None (0)'	System	23 Aug 2020 16:05:48



US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:05:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-23T12:04:05', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'd871307c-a48e-4bd8-9459-49ca5c1e88c5'	System	23 Aug 2020 16:05:48
User entered 'None (0)'	System	23 Aug 2020 16:05:48

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:05:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-23T12:04:09', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'd871307c-a48e-4bd8-9459-49ca5c1e88c5'	System	23 Aug 2020 16:05:48
User entered 'None (0)'	System	23 Aug 2020 16:05:48

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:05:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-23T12:04:12', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'd871307c-a48e-4bd8-9459-49ca5c1e88c5'	System	23 Aug 2020 16:05:48
User entered 'None (0)'	System	23 Aug 2020 16:05:48

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-23T12:04:30', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'd871307c-a48e-4bd8-9459-49ca5c1e88c5'	System	23 Aug 2020 16:05:48
User entered 'No (N)'	System	23 Aug 2020 16:05:48

**US3172265**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:05:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-23T12:04:34', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'd871307c-a48e-4bd8-9459-49ca5c1e88c5'	System	23 Aug 2020 16:05:48
User entered '23 Aug 2020 12:04'	System	23 Aug 2020 16:05:48

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered 'Day 4'	System	21 Aug 2020 16:19:01



US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:05:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-24T13:55:12', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '843729c0-ef14-44a8-b5d8-e492aec43d1a'	System	24 Aug 2020 17:56:48
User entered 'None (0)'	System	24 Aug 2020 17:56:48

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:05:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-24T13:55:14', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '843729c0-ef14-44a8-b5d8-e492aec43d1a'	System	24 Aug 2020 17:56:48
User entered 'None (0)'	System	24 Aug 2020 17:56:48

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:05:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-24T13:55:19', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '843729c0-ef14-44a8-b5d8-e492aec43d1a'	System	24 Aug 2020 17:56:48
User entered 'None (0)'	System	24 Aug 2020 17:56:48

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:05:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-24T13:55:23', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '843729c0-ef14-44a8-b5d8-e492aec43d1a'	System	24 Aug 2020 17:56:48
User entered 'None (0)'	System	24 Aug 2020 17:56:48

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:05:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-24T13:55:26', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '843729c0-ef14-44a8-b5d8-e492aec43d1a'	System	24 Aug 2020 17:56:48
User entered 'None (0)'	System	24 Aug 2020 17:56:48

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:05:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-24T13:55:28', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '843729c0-ef14-44a8-b5d8-e492aec43d1a'	System	24 Aug 2020 17:56:48
User entered 'None (0)'	System	24 Aug 2020 17:56:48

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-24T13:55:32', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '843729c0-ef14-44a8-b5d8-e492aec43d1a'	System	24 Aug 2020 17:56:48
User entered 'No (N)'	System	24 Aug 2020 17:56:48

**US3172265**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:05:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-24T13:55:34', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '843729c0-ef14-44a8-b5d8-e492aec43d1a'	System	24 Aug 2020 17:56:48
User entered '24 Aug 2020 13:55'	System	24 Aug 2020 17:56:48



US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered 'Day 5'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:05:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-25T16:12:17', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '3b773d83-f4ac-4cd2-87dd-51b7a1cf55c7'	System	25 Aug 2020 20:13:51
User entered 'None (0)'	System	25 Aug 2020 20:13:51

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:05:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-25T16:12:19', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '3b773d83-f4ac-4cd2-87dd-51b7a1cf55c7'	System	25 Aug 2020 20:13:51
User entered 'None (0)'	System	25 Aug 2020 20:13:51

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:05:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-25T16:12:20', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '3b773d83-f4ac-4cd2-87dd-51b7a1cf55c7'	System	25 Aug 2020 20:13:51
User entered 'None (0)'	System	25 Aug 2020 20:13:51

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:05:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-25T16:12:21', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '3b773d83-f4ac-4cd2-87dd-51b7a1cf55c7'	System	25 Aug 2020 20:13:51
User entered 'None (0)'	System	25 Aug 2020 20:13:51

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:05:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-25T16:12:22', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '3b773d83-f4ac-4cd2-87dd-51b7a1cf55c7'	System	25 Aug 2020 20:13:51
User entered 'None (0)'	System	25 Aug 2020 20:13:51



US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:05:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-25T16:12:24', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '3b773d83-f4ac-4cd2-87dd-51b7a1cf55c7'	System	25 Aug 2020 20:13:51
User entered 'None (0)'	System	25 Aug 2020 20:13:51

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-25T16:12:27', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '3b773d83-f4ac-4cd2-87dd-51b7a1cf55c7'	System	25 Aug 2020 20:13:51
User entered 'No (N)'	System	25 Aug 2020 20:13:51

**US3172265**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:05:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-25T16:12:28', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '3b773d83-f4ac-4cd2-87dd-51b7a1cf55c7'	System	25 Aug 2020 20:13:51
User entered '25 Aug 2020 16:12'	System	25 Aug 2020 20:13:51

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered 'Day 6'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:05:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-26T12:00:57', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '5f13aa1f-422b-4e2b-802e-20575a4863d9'	System	26 Aug 2020 16:02:52
User entered 'None (0)'	System	26 Aug 2020 16:02:52

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:05:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-26T12:00:58', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '5f13aa1f-422b-4e2b-802e-20575a4863d9'	System	26 Aug 2020 16:02:52
User entered 'None (0)'	System	26 Aug 2020 16:02:52



US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:05:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-26T12:00:59', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '5f13aa1f-422b-4e2b-802e-20575a4863d9'	System	26 Aug 2020 16:02:52
User entered 'None (0)'	System	26 Aug 2020 16:02:52

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:05:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-26T12:01:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '5f13aa1f-422b-4e2b-802e-20575a4863d9'	System	26 Aug 2020 16:02:52
User entered 'None (0)'	System	26 Aug 2020 16:02:52

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:05:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-26T12:01:01', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '5f13aa1f-422b-4e2b-802e-20575a4863d9'	System	26 Aug 2020 16:02:52
User entered 'None (0)'	System	26 Aug 2020 16:02:52

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:05:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-26T12:01:02', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '5f13aa1f-422b-4e2b-802e-20575a4863d9'	System	26 Aug 2020 16:02:52
User entered 'None (0)'	System	26 Aug 2020 16:02:52

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-26T12:01:05', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '5f13aa1f-422b-4e2b-802e-20575a4863d9'	System	26 Aug 2020 16:02:52
User entered 'No (N)'	System	26 Aug 2020 16:02:52

**US3172265**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:05:08**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-26T12:01:06', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '5f13aa1f-422b-4e2b-802e-20575a4863d9'	System	26 Aug 2020 16:02:52
User entered '26 Aug 2020 12:01'	System	26 Aug 2020 16:02:52

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:05:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 16:19:01



US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered 'Day 7'	System	21 Aug 2020 16:19:01

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:05:08

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-27T23:59:51', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '4321001f-af6d-4a8b-b91a-6299ed8a8bc1'	System	28 Aug 2020 04:01:16
User entered 'None (0)'	System	28 Aug 2020 04:01:16

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:05:08

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-27T23:59:52', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '4321001f-af6d-4a8b-b91a-6299ed8a8bc1'	System	28 Aug 2020 04:01:16
User entered 'None (0)'	System	28 Aug 2020 04:01:16

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:05:08

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-27T23:59:53', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '4321001f-af6d-4a8b-b91a-6299ed8a8bc1'	System	28 Aug 2020 04:01:16
User entered 'None (0)'	System	28 Aug 2020 04:01:16

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:05:08

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-27T23:59:54', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '4321001f-af6d-4a8b-b91a-6299ed8a8bc1'	System	28 Aug 2020 04:01:16
User entered 'None (0)'	System	28 Aug 2020 04:01:16

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:05:08

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-27T23:59:55', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '4321001f-af6d-4a8b-b91a-6299ed8a8bc1'	System	28 Aug 2020 04:01:16
User entered 'None (0)'	System	28 Aug 2020 04:01:16

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:05:08

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-27T23:59:56', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '4321001f-af6d-4a8b-b91a-6299ed8a8bc1'	System	28 Aug 2020 04:01:16
User entered 'None (0)'	System	28 Aug 2020 04:01:16

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-27T23:59:59', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '4321001f-af6d-4a8b-b91a-6299ed8a8bc1'	System	28 Aug 2020 04:01:16
User entered 'No (N)'	System	28 Aug 2020 04:01:16



US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:05:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (590a630d8f163d40)', Time: '2020-08-28T00:00:01', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '4321001f-af6d-4a8b-b91a-6299ed8a8bc1'	System	28 Aug 2020 04:01:16
User entered '28 Aug 2020 00:00'	System	28 Aug 2020 04:01:16

US3172265

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:05:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 16:19:01

**US3172265**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:05:08**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 16:19:01

US3172265

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 21:36:45

US3172265

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '31 Aug 2020'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 21:36:45

US3172265

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 21:36:45

US3172265

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 21:36:45

US3172265

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 21:36:52



US3172265

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered 'I'	System	31 Aug 2020 21:36:52

US3172265

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	08 Sep 2020 20:44:44

US3172265

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '05 Sep 2020'	Jessie Downs (b) (4) (b) (4)	08 Sep 2020 20:44:44

US3172265

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	08 Sep 2020 20:44:44

US3172265

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	08 Sep 2020 20:44:44

US3172265

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	08 Sep 2020 20:44:48

US3172265

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered 'I'	System	08 Sep 2020 20:44:48

US3172265

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	14 Sep 2020 20:11:16



US3172265

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '14 Sep 2020'	Jessie Downs (b) (4) (b) (4)	14 Sep 2020 20:11:16

US3172265

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	14 Sep 2020 20:11:16

US3172265

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Sep 2020 20:11:16

US3172265

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	14 Sep 2020 20:11:21

US3172265

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered 'I'	System	14 Sep 2020 20:11:21

US3172265

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:35:58

US3172265

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:08

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered '18 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:35:58

US3172265

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:08

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:35:58



**US3172265**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:08**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered 'VISIT2'	System	21 Sep 2020 19:35:58

US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User accepted default value 'Pre-Dose (PREDOSE)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:39:44

US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:39:44

US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered '18 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:39:44

US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:18:23
	(b) (4)	
User entered '10:25'	Mariete Rendon (b) (4)	21 Sep 2020 19:39:44
	(b) (4)	

US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered '18 Sep 2020 10:25'	System	21 Sep 2020 19:39:44

US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered '36.6' C	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:39:44

US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:39:44



US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:39:44

US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered '76'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:39:44

US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered 'bpm'	System	21 Sep 2020 19:39:44

US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered '15'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:39:44

US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered 'breaths/min'	System	21 Sep 2020 19:39:44

US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered '117'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:39:44

US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered 'mmHg'	System	21 Sep 2020 19:39:44

US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered '80'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:39:44



US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered 'mmHg'	System	21 Sep 2020 19:39:44

US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User accepted default value 'Post-Dose (POSTDOSE)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:39:44

US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:39:44

US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:39:44

US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:18:23
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	21 Sep 2020 19:39:44
	(b) (4)	

US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered empty.	System	21 Sep 2020 19:39:44

US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User closed query 'Per DM: Data is required. Please updated.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 18:19:23
Query 'Per DM: Data is required. Please updated.' answered with 'Subject was not dose for safety reasons. Subject had a systemic hypersensitivity reaction after 1st dose of IP. AE recovered and resolved.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 15:26:25
User opened query 'Per DM: Data is required. Please updated.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 14:35:41
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:39:44

US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:39:44



US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:39:44

US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User closed query 'Per DM: Data is required. Please updated.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 18:19:34
Query 'Per DM: Data is required. Please updated.' answered with 'Subject was not dose for safety reasons. Subject had a systemic hypersensitivity reaction after 1st dose of IP. AE recovered and resolved.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 15:26:28
User opened query 'Per DM: Data is required. Please updated.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 14:35:48
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:39:44

US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered empty.	System	21 Sep 2020 19:39:44

US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User closed query 'Per DM: Data is required. Please updated.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 18:19:37
Query 'Per DM: Data is required. Please updated.' answered with 'Subject was not dose for safety reasons. Subject had a systemic hypersensitivity reaction after 1st dose of IP. AE recovered and resolved.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 15:26:31
User opened query 'Per DM: Data is required. Please updated.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 14:35:56
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:39:44

US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered empty.	System	21 Sep 2020 19:39:44

US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User closed query 'Per DM: Data is required. Please updated.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 18:19:40
Query 'Per DM: Data is required. Please updated.' answered with 'Subject was not dose for safety reasons. Subject had a systemic hypersensitivity reaction after 1st dose of IP. AE recovered and resolved.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 15:26:35
User opened query 'Per DM: Data is required. Please updated.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 14:36:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:39:44

US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered empty.	System	21 Sep 2020 19:39:44

US3172265

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User closed query 'Per DM: Data is required. Please updated.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 18:19:43
Query 'Per DM: Data is required. Please updated.' answered with 'Subject was not dose for safety reasons. Subject had a systemic hypersensitivity reaction after 1st dose of IP. AE recovered and resolved.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 15:26:37
User opened query 'Per DM: Data is required. Please updated.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 14:36:12
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:39:44



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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered empty.	System	21 Sep 2020 19:39:44

US3172265

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:40:08

US3172265

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:08

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '18 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:40:08

US3172265

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:40:51

US3172265

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:18:07
	(b) (4)	
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	Mariete Rendon (b) (4)	21 Sep 2020 19:40:51
	(b) (4)	

US3172265

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:40:51

US3172265

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered empty.	System	21 Sep 2020 19:40:51

US3172265

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:40:51



US3172265

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:40:51

US3172265

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered empty.	System	21 Sep 2020 19:40:51

US3172265

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:40:51

US3172265

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered empty.	System	21 Sep 2020 19:40:51

US3172265

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered empty.	System	21 Sep 2020 19:40:51

US3172265

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:41:08

US3172265

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '18 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:41:08

US3172265

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '11:32'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:41:08



US3172265

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:08

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered '18 Sep 2020 11:32'	System	21 Sep 2020 19:41:08

US3172265

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:05:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '18 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:41:17

US3172265

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:41:17

US3172265

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:41:17

US3172265

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '11:29'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:41:17

US3172265

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:05:08

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered '18 Sep 2020 11:29'	System	21 Sep 2020 19:41:17

US3172265

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:41:17

US3172265

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:41:17



US3172265

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:41:17

US3172265

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:05:08

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered empty.	System	21 Sep 2020 19:41:17

US3172265

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 19:41:45

US3172265

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered '1'	System	21 Sep 2020 19:41:45

US3172265

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 15:22:29

US3172265

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:18:07
	(b) (4)	
User entered '25 Sep 2020'	Jessie Downs (b) (4)	29 Sep 2020 15:22:29
	(b) (4)	

US3172265

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 15:22:29

US3172265

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 15:22:29



US3172265

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 15:22:33

US3172265

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered 'I'	System	29 Sep 2020 15:22:33

US3172265

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 20:08:07

US3172265

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '05 Oct 2020'	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 20:08:07

US3172265

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 20:08:07

US3172265

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 20:08:07

US3172265

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 18:45:30
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	08 Oct 2020 17:56:28
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 20:08:13

US3172265

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered '1'	System	23 Oct 2020 18:45:30
User entered empty.	System	08 Oct 2020 17:56:28
User entered '1'	System	05 Oct 2020 20:08:13



US3172265

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 18:45:42

US3172265

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '9 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 18:45:42

US3172265

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 18:45:48
User entered 'Contact Not Made (CONTACT NOT MADE)'	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 18:45:42

US3172265

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	23 Oct 2020 18:45:48
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	23 Oct 2020 18:45:42
User entered empty.	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 18:45:42

US3172265

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 18:45:52

US3172265

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered 'I'	System	23 Oct 2020 18:45:52

US3172265

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 18:53:26

US3172265

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:08

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered '23 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 18:53:26



US3172265

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:08

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 18:53:26

**US3172265**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:08**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered 'VISIT3'	System	23 Oct 2020 18:53:26

US3172265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 18:53:49

US3172265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered '23 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 18:53:49

US3172265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:18:23
	(b) (4)	
User entered '11:55'	Mariete Rendon (b) (4)	23 Oct 2020 18:53:49
	(b) (4)	

US3172265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered '23 Oct 2020 11:55'	System	23 Oct 2020 18:53:49

US3172265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered '36.8' C	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 18:53:49

US3172265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 18:53:49



US3172265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered empty.	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 18:53:49

US3172265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered '66'	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 18:53:49

US3172265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered 'bpm'	System	23 Oct 2020 18:53:49

US3172265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered '14'	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 18:53:49

US3172265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered 'breaths/min'	System	23 Oct 2020 18:53:49

US3172265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered '126'	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 18:53:49

US3172265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered 'mmHg'	System	23 Oct 2020 18:53:49

US3172265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered '84'	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 18:53:49



US3172265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered 'mmHg'	System	23 Oct 2020 18:53:49

US3172265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18

US3172265

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18

US3172265

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 18:53:55

US3172265

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:08

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered empty.	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 18:53:55

US3172265

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 18:54:02

US3172265

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered '23 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 18:54:02

US3172265

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered '12:52'	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 18:54:02



US3172265

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:08

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered '23 Oct 2020 12:52'	System	23 Oct 2020 18:54:02

US3172265

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 20:41:11
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 18:54:21

US3172265

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered '1'	System	16 Nov 2020 20:41:11
User entered empty.	System	23 Oct 2020 18:54:21

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered 'Day 64'	System	21 Aug 2020 16:19:01

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-10-23T12:11:10', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '9343948f-e75e-4716-b546-5f95d417f190' User entered 'No (N)'	System	23 Oct 2020 16:11:19
	System	23 Oct 2020 16:11:19

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-10-23T12:11:13', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '9343948f-e75e-4716-b546-5f95d417f190'	System	23 Oct 2020 16:11:19
User entered 'No (N)'	System	23 Oct 2020 16:11:19

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-10-23T12:11:16', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '9343948f-e75e-4716-b546-5f95d417f190' User entered '23 Oct 2020 12:11:16'	System	23 Oct 2020 16:11:19
	System	23 Oct 2020 16:11:19

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered '21 Oct 2020 00:01'	System	21 Aug 2020 16:19:01



US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered '25 Oct 2020 23:59'	System	21 Aug 2020 16:19:01

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered 'Day 71'	System	21 Aug 2020 16:19:01

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-10-28T02:17:54', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'f76f7b9e-e8e0-4e75-bea6-e39222356515' User entered 'No (N)'	System	28 Oct 2020 06:18:04
	System	28 Oct 2020 06:18:04

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-10-28T02:17:57', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'f76f7b9e-e8e0-4e75-bea6-e39222356515'	System	28 Oct 2020 06:18:04
User entered 'No (N)'	System	28 Oct 2020 06:18:04

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-10-28T02:18:01', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'f76f7b9e-e8e0-4e75-bea6-e39222356515' User entered '28 Oct 2020 02:18:01'	System	28 Oct 2020 06:18:04
	System	28 Oct 2020 06:18:04

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered '28 Oct 2020 00:01'	System	21 Aug 2020 16:19:01

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered '01 Nov 2020 23:59'	System	21 Aug 2020 16:19:01

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered 'Day 78'	System	21 Aug 2020 16:19:01



US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-11-04T00:01:20', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '4fe82e30-2054-4f34-ae03-e04e2bc25812'	System	04 Nov 2020 05:01:33
User entered 'No (N)'	System	04 Nov 2020 05:01:33

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-11-04T00:01:24', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '4fe82e30-2054-4f34-ae03-e04e2bc25812'	System	04 Nov 2020 05:01:33
User entered 'No (N)'	System	04 Nov 2020 05:01:33

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-11-04T00:01:30', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '4fe82e30-2054-4f34-ae03-e04e2bc25812' User entered '04 Nov 2020 00:01:30'	System	04 Nov 2020 05:01:33
	System	04 Nov 2020 05:01:33

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered '04 Nov 2020 00:01'	System	21 Aug 2020 16:19:01

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:35:28
Data entry locked.	System	21 Aug 2020 16:19:01
User entered '08 Nov 2020 23:59'	System	21 Aug 2020 16:19:01

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:38:36
Data entry locked.	System	21 Aug 2020 16:19:01
User entered 'Day 92'	System	21 Aug 2020 16:19:01

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:38:36

US3172265

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:38:36



**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:38:36

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:38:36

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:38:36

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:38:36

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:38:36

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:38:36

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:38:36

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:38:36



US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:38:36

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:38:36

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:38:36

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:38:36

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:38:36

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:38:36

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:38:36



US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:38:36

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:38:36

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:38:36

US3172265

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:38:36

US3172265

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:38:36
Data entry locked.	System	21 Aug 2020 16:19:01
User entered '18 Nov 2020 00:01'	System	21 Aug 2020 16:19:01



**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:38:36
Data entry locked.	System	21 Aug 2020 16:19:01
User entered '22 Nov 2020 23:59'	System	21 Aug 2020 16:19:01

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-11-19T21:26:05', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '9628922f-c719-4723-b30f-a966dec41cb9'	System	20 Nov 2020 02:26:13
User entered 'No (N)'	System	20 Nov 2020 02:26:13

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

Have you been exposed to someone with 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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-11-19T21:26:06', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '9628922f-c719-4723-b30f-a966dec41cb9' User entered 'No (N)'	System	20 Nov 2020 02:26:13

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-11-19T21:26:09', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '9628922f-c719-4723-b30f-a966dec41cb9' User entered '19 Nov 2020 21:26:09'	System	20 Nov 2020 02:26:13
	System	20 Nov 2020 02:26:13

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '15 Nov 2020 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '19 Nov 2020 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:38:36



**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-11-22T00:01:18', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'bf23889d-ed0a-4f71-bc4a-2d28a244b751'	System	22 Nov 2020 05:01:29
User entered 'No (N)'	System	22 Nov 2020 05:01:29

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

Have you been exposed to someone with 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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-11-22T00:01:20', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'bf23889d-ed0a-4f71-bc4a-2d28a244b751'	System	22 Nov 2020 05:01:29
User entered 'No (N)'	System	22 Nov 2020 05:01:29

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-11-22T00:01:23', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'bf23889d-ed0a-4f71-bc4a-2d28a244b751' User entered '22 Nov 2020 00:01:23'	System	22 Nov 2020 05:01:29
	System	22 Nov 2020 05:01:29

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:38:36

US3172265

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-11-29T00:02:08', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '88ec5322-af63-440d-98b8-baffb8a1aef8' User entered 'No (N)'	System	29 Nov 2020 05:02:36
	System	29 Nov 2020 05:02:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

Have you been exposed to someone with 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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-11-29T00:02:10', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '88ec5322-af63-440d-98b8-baffb8a1aef8' User entered 'No (N)'	System	29 Nov 2020 05:02:36



**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-11-29T00:02:12', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '88ec5322-af63-440d-98b8-baffb8a1aef8' User entered '29 Nov 2020 00:02:12'	System	29 Nov 2020 05:02:36
	System	29 Nov 2020 05:02:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 00:38:36

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-12-07T13:11:33', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '11739754-2246-476c-873a-53d76b22f7df'	System	07 Dec 2020 18:11:40
User entered 'No (N)'	System	07 Dec 2020 18:11:40

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Have you been exposed to someone with 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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-12-07T13:11:34', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '11739754-2246-476c-873a-53d76b22f7df' User entered 'No (N)'	System	07 Dec 2020 18:11:40
	System	07 Dec 2020 18:11:40

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-12-07T13:11:36', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '11739754-2246-476c-873a-53d76b22f7df' User entered '07 Dec 2020 13:11:36'	System	07 Dec 2020 18:11:40
	System	07 Dec 2020 18:11:40

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 00:38:36



**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-12-13T00:05:32', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'ee8904cf-4ddc-4431-863f-dd5aa8e3c070'	System	13 Dec 2020 05:05:41
User entered 'No (N)'	System	13 Dec 2020 05:05:41

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

Have you been exposed to someone with 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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-12-13T00:05:35', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'ee8904cf-4ddc-4431-863f-dd5aa8e3c070'	System	13 Dec 2020 05:05:41
User entered 'No (N)'	System	13 Dec 2020 05:05:41

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-12-13T00:05:39', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'ee8904cf-4ddc-4431-863f-dd5aa8e3c070' User entered '13 Dec 2020 00:05:39'	System	13 Dec 2020 05:05:41
	System	13 Dec 2020 05:05:41

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:38:36



**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-12-20T02:35:36', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '0b33aa3a-bc95-4858-bd55-59e1652dd00f' User entered 'No (N)'	System	20 Dec 2020 07:35:53
	System	20 Dec 2020 07:35:53

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

Have you been exposed to someone with 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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-12-20T02:35:49', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '0b33aa3a-bc95-4858-bd55-59e1652dd00f' User entered 'No (N)'	System	20 Dec 2020 07:35:53
	System	20 Dec 2020 07:35:53

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-12-20T02:35:51', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '0b33aa3a-bc95-4858-bd55-59e1652dd00f' User entered '20 Dec 2020 02:35:51'	System	20 Dec 2020 07:35:53
	System	20 Dec 2020 07:35:53

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-12-27T00:01:43', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'dc20a317-79fc-43e1-ae1d-342a09df25d3'	System	27 Dec 2020 05:02:13
User entered 'No (N)'	System	27 Dec 2020 05:02:13

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

Have you been exposed to someone with 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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-12-27T00:01:44', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'dc20a317-79fc-43e1-ae1d-342a09df25d3'	System	27 Dec 2020 05:02:13
User entered 'No (N)'	System	27 Dec 2020 05:02:13



**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2020-12-27T00:01:47', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'dc20a317-79fc-43e1-ae1d-342a09df25d3' User entered '27 Dec 2020 00:01:47'	System	27 Dec 2020 05:02:13

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-01-05T19:39:17', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '87ea05ba-6858-43db-b9dd-def2a87e3be7'	System	06 Jan 2021 00:39:26
User entered 'No (N)'	System	06 Jan 2021 00:39:26

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Have you been exposed to someone with 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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-01-05T19:39:18', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '87ea05ba-6858-43db-b9dd-def2a87e3be7'	System	06 Jan 2021 00:39:26
User entered 'No (N)'	System	06 Jan 2021 00:39:26

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-01-05T19:39:20', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '87ea05ba-6858-43db-b9dd-def2a87e3be7' User entered '05 Jan 2021 19:39:20'	System	06 Jan 2021 00:39:26
	System	06 Jan 2021 00:39:26

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 00:38:36



**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-01-10T00:12:20', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '80483369-ddf2-4ff7-a0b8-2e6d1ceca733'	System	10 Jan 2021 05:13:34
User entered 'No (N)'	System	10 Jan 2021 05:13:34

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

Have you been exposed to someone with 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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-01-10T00:12:22', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '80483369-ddf2-4ff7-a0b8-2e6d1ceca733'	System	10 Jan 2021 05:13:34
User entered 'No (N)'	System	10 Jan 2021 05:13:34

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-01-10T00:12:24', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '80483369-ddf2-4ff7-a0b8-2e6d1ceca733' User entered '10 Jan 2021 00:12:24'	System	10 Jan 2021 05:13:34
	System	10 Jan 2021 05:13:34

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:38:36



**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-01-17T00:01:45', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '0d4d5d5d-fdca-4ba2-9c0f-d472a0ec45ea'	System	17 Jan 2021 05:02:13
User entered 'No (N)'	System	17 Jan 2021 05:02:13

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

Have you been exposed to someone with 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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-01-17T00:01:53', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '0d4d5d5d-fdca-4ba2-9c0f-d472a0ec45ea' User entered 'No (N)'	System	17 Jan 2021 05:02:13
	System	17 Jan 2021 05:02:13

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-01-17T00:01:56', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '0d4d5d5d-fdca-4ba2-9c0f-d472a0ec45ea' User entered '17 Jan 2021 00:01:56'	System	17 Jan 2021 05:02:13
	System	17 Jan 2021 05:02:13

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-01-24T00:01:36', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '29839bb4-f5c4-4614-b21e-c16657c77b41' User entered 'No (N)'	System	24 Jan 2021 05:02:11
	System	24 Jan 2021 05:02:11

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

Have you been exposed to someone with 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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-01-24T00:01:39', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '29839bb4-f5c4-4614-b21e-c16657c77b41'	System	24 Jan 2021 05:02:11
User entered 'No (N)'	System	24 Jan 2021 05:02:11



**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-01-24T00:01:41', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '29839bb4-f5c4-4614-b21e-c16657c77b41' User entered '24 Jan 2021 00:01:41'	System	24 Jan 2021 05:02:11

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-01-31T00:01:41', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '3e1ab4d6-baf5-402c-bdce-c72908d8907b' User entered 'No (N)'	System	31 Jan 2021 05:02:11
	System	31 Jan 2021 05:02:11

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

Have you been exposed to someone with 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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-01-31T00:01:42', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '3e1ab4d6-baf5-402c-bdce-c72908d8907b' User entered 'No (N)'	System	31 Jan 2021 05:02:11
	System	31 Jan 2021 05:02:11

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-01-31T00:01:44', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '3e1ab4d6-baf5-402c-bdce-c72908d8907b' User entered '31 Jan 2021 00:01:44'	System	31 Jan 2021 05:02:11
	System	31 Jan 2021 05:02:11

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 00:38:36



**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-02-07T00:01:37', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'a5b1149a-a055-4b13-91d6-a8a2cbd5c13b' User entered 'No (N)'	System	07 Feb 2021 05:02:22
	System	07 Feb 2021 05:02:22

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

Have you been exposed to someone with 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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-02-07T00:01:38', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'a5b1149a-a055-4b13-91d6-a8a2cbd5c13b' User entered 'No (N)'	System	07 Feb 2021 05:02:22
	System	07 Feb 2021 05:02:22

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-02-07T00:01:53', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'a5b1149a-a055-4b13-91d6-a8a2cbd5c13b' User entered '07 Feb 2021 00:01:53'	System	07 Feb 2021 05:02:22

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:38:36



**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-02-14T00:06:01', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'df20e9d3-24f2-4b38-b18f-6ffb61500c76'	System	14 Feb 2021 05:06:09
User entered 'No (N)'	System	14 Feb 2021 05:06:09

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Have you been exposed to someone with 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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-02-14T00:06:03', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'df20e9d3-24f2-4b38-b18f-6ffb61500c76'	System	14 Feb 2021 05:06:09
User entered 'No (N)'	System	14 Feb 2021 05:06:09

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-02-14T00:06:05', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'df20e9d3-24f2-4b38-b18f-6ffb61500c76'	System	14 Feb 2021 05:06:09
User entered '14 Feb 2021 00:06:05'	System	14 Feb 2021 05:06:09

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-02-21T00:01:10', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '134f5ddb-7f59-4cf4-a5e1-0d7adc23e910'	System	21 Feb 2021 05:01:48
User entered 'No (N)'	System	21 Feb 2021 05:01:48

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

Have you been exposed to someone with 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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-02-21T00:01:12', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '134f5ddb-7f59-4cf4-a5e1-0d7adc23e910'	System	21 Feb 2021 05:01:48
User entered 'No (N)'	System	21 Feb 2021 05:01:48



**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-02-21T00:01:14', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '134f5ddb-7f59-4cf4-a5e1-0d7adc23e910' User entered '21 Feb 2021 00:01:14'	System	21 Feb 2021 05:01:48
	System	21 Feb 2021 05:01:48

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-02-28T00:11:06-05:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '64422d34-8e0e-43d6-8842-8c6c53d33711'	System	28 Feb 2021 05:11:13
User entered 'No (N)'	System	28 Feb 2021 05:11:13

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

Have you been exposed to someone with 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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-02-28T00:11:07-05:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '64422d34-8e0e-43d6-8842-8c6c53d33711'	System	28 Feb 2021 05:11:13
User entered 'No (N)'	System	28 Feb 2021 05:11:13

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-02-28T00:11:09-05:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '64422d34-8e0e-43d6-8842-8c6c53d33711'	System	28 Feb 2021 05:11:13
User entered '28 Feb 2021 05:11:09'	System	28 Feb 2021 05:11:13

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 00:38:36



**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:38:36

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-03-07T00:02:29-05:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '3c75781c-d11a-4a6c-94dc-8b9783bae556'	System	07 Mar 2021 05:04:21
User entered 'No (N)'	System	07 Mar 2021 05:04:21

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

Have you been exposed to someone with 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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-03-07T00:02:32-05:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '3c75781c-d11a-4a6c-94dc-8b9783bae556'	System	07 Mar 2021 05:04:21
User entered 'No (N)'	System	07 Mar 2021 05:04:21

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-03-07T00:02:34-05:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '3c75781c-d11a-4a6c-94dc-8b9783bae556' User entered '07 Mar 2021 00:02:34'	System	07 Mar 2021 05:04:21
	System	07 Mar 2021 05:04:21

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:38:36



**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-03-14T00:02:17-05:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'b1ba6cbe-1d39-400f-a906-7d2f365920dd'	System	14 Mar 2021 05:05:50
User entered 'No (N)'	System	14 Mar 2021 05:05:50

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

Have you been exposed to someone with 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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-03-14T00:02:20-05:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'b1ba6cbe-1d39-400f-a906-7d2f365920dd'	System	14 Mar 2021 05:05:50
User entered 'No (N)'	System	14 Mar 2021 05:05:50

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-03-14T00:02:22-05:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'b1ba6cbe-1d39-400f-a906-7d2f365920dd' User entered '14 Mar 2021 00:02:22'	System	14 Mar 2021 05:05:50
	System	14 Mar 2021 05:05:50

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-03-21T00:02:27-04:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'cb4a7307-1f5c-4076-a40b-67b5fe95b570'	System	21 Mar 2021 04:03:13
User entered 'No (N)'	System	21 Mar 2021 04:03:13

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

Have you been exposed to someone with 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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-03-21T00:02:30-04:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'cb4a7307-1f5c-4076-a40b-67b5fe95b570'	System	21 Mar 2021 04:03:13
User entered 'No (N)'	System	21 Mar 2021 04:03:13



**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-03-21T00:02:33-04:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'cb4a7307-1f5c-4076-a40b-67b5fe95b570'	System	21 Mar 2021 04:03:13
User entered '21 Mar 2021 00:02:33'	System	21 Mar 2021 04:03:13

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-03-28T00:02:26-04:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'a4d0902c-71a7-4d11-b20e-ae44a8ea216f' User entered 'No (N)'	System	01 Apr 2021 14:00:05
	System	01 Apr 2021 14:00:05

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

Have you been exposed to someone with 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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-03-28T00:02:28-04:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'a4d0902c-71a7-4d11-b20e-ae44a8ea216f' User entered 'No (N)'	System	01 Apr 2021 14:00:05

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-03-28T00:02:29-04:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'a4d0902c-71a7-4d11-b20e-ae44a8ea216f' User entered '28 Mar 2021 00:02:29'	System	01 Apr 2021 14:00:05
	System	01 Apr 2021 14:00:05

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 00:38:36



**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-04-04T00:02:16-04:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'b8e13bb3-9114-4f78-a266-f110dcba99cb' User entered 'No (N)'	System	04 Apr 2021 04:03:22
	System	04 Apr 2021 04:03:22

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

Have you been exposed to someone with 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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-04-04T00:02:18-04:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'b8e13bb3-9114-4f78-a266-f110dcba99cb' User entered 'No (N)'	System	04 Apr 2021 04:03:22
	System	04 Apr 2021 04:03:22

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-04-04T00:02:19-04:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'b8e13bb3-9114-4f78-a266-f110dcba99cb' User entered '04 Apr 2021 00:02:19'	System	04 Apr 2021 04:03:22
	System	04 Apr 2021 04:03:22

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:38:36



**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-04-11T00:02:16-04:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '7768b33b-0688-4487-b868-015477e1ceca'	System	11 Apr 2021 04:03:16
User entered 'No (N)'	System	11 Apr 2021 04:03:16

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

Have you been exposed to someone with 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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-04-11T00:02:18-04:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '7768b33b-0688-4487-b868-015477e1ceca'	System	11 Apr 2021 04:03:16
User entered 'No (N)'	System	11 Apr 2021 04:03:16

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-04-11T00:02:19-04:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '7768b33b-0688-4487-b868-015477e1ceca'	System	11 Apr 2021 04:03:16
User entered '11 Apr 2021 00:02:19'	System	11 Apr 2021 04:03:16

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:38:36

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

[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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-04-18T00:05:08-04:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '5f8b0335-fb6d-4f11-a4d0-76ddf6b76f96'	System	18 Apr 2021 04:05:14
User entered 'No (N)'	System	18 Apr 2021 04:05:14

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

Have you been exposed to someone with 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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-04-18T00:05:09-04:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '5f8b0335-fb6d-4f11-a4d0-76ddf6b76f96'	System	18 Apr 2021 04:05:14
User entered 'No (N)'	System	18 Apr 2021 04:05:14



**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-04-18T00:05:11-04:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '5f8b0335-fb6d-4f11-a4d0-76ddf6b76f96'	System	18 Apr 2021 04:05:14
User entered '18 Apr 2021 00:05:11'	System	18 Apr 2021 04:05:14

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-04-26T09:33:40-04:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'fc0bc19e-571f-43dd-bcdc-786ae9a2a56b'	System	26 Apr 2021 13:33:50
User entered 'No (N)'	System	26 Apr 2021 13:33:50

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

Have you been exposed to someone with 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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-04-26T09:33:42-04:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'fc0bc19e-571f-43dd-bcdc-786ae9a2a56b'	System	26 Apr 2021 13:33:50
User entered 'No (N)'	System	26 Apr 2021 13:33:50

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-04-26T09:33:44-04:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'fc0bc19e-571f-43dd-bcdc-786ae9a2a56b' User entered '26 Apr 2021 09:33:44'	System	26 Apr 2021 13:33:50
	System	26 Apr 2021 13:33:50

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 00:38:36



**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-05-02T00:02:23-04:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '61905579-cc05-4396-8794-6c9bba7718ff'	System	02 May 2021 04:03:53
User entered 'No (N)'	System	02 May 2021 04:03:53

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

Have you been exposed to someone with 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 (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-05-02T00:02:24-04:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '61905579-cc05-4396-8794-6c9bba7718ff'	System	02 May 2021 04:03:53
User entered 'No (N)'	System	02 May 2021 04:03:53

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-05-02T00:02:27-04:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: '61905579-cc05-4396-8794-6c9bba7718ff'	System	02 May 2021 04:03:53
User entered '02 May 2021 00:02:27'	System	02 May 2021 04:03:53

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:38:36



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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 00:38:36

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 00:38:36



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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 00:38:36

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 00:38:36



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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 00:38:36

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:38:36

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 00:38:36

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:38:36



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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 00:38:36

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 00:38:36

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 00:38:36

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 00:38:36

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 00:38:36



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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 00:38:36

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 00:38:36

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

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**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 00:38:36



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

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**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:38:36



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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 00:38:36

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

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**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 00:38:36



**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 00:38:36



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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 00:38:36

US3172265

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:05:08

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:38:36



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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 00:38:36

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 00:38:36



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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 00:38:36



**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:38:36



**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 00:38:36



**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:38:36

**US3172265**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 00:38:36



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:38:36



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 00:38:36



**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 00:38:36



**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:38:36



**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 00:38:36



**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 00:38:36



**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:38:36



**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 00:38:36



**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 00:38:36



**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:38:36



**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 00:38:36



**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 00:38:36



**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:38:36



**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 00:38:36



**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 00:38:36

**US3172265**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:05:08**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:38:36
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 00:38:36

US3172265

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:05:08

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-02-28T00:11:15-05:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'e45480dd-f529-40e4-9e7b-154a1cb9ffee'	System	28 Feb 2021 05:11:21
User entered 'No (N)'	System	28 Feb 2021 05:11:21

**US3172265**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:05:08**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7AE9FBFC-F8AA-441A-A9AD-84F0F16A8E4D)', Time: '2021-02-28T00:11:18-05:00', User OID: 'PatientReportedOutcome (US3172265)', ODM File OID: 'e45480dd-f529-40e4-9e7b-154a1cb9ffee'	System	28 Feb 2021 05:11:21
User entered '28 Feb 2021 05:11:18'	System	28 Feb 2021 05:11:21



US3172265

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 20:41:28

US3172265

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:18:07
	(b) (4)	
User entered '13 Nov 2020'	Jessie Downs (b) (4)	16 Nov 2020 20:41:28
	(b) (4)	

US3172265

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 20:41:28

US3172265

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 20:41:28

US3172265

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 20:41:55

US3172265

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:15:18
User entered '1'	System	16 Nov 2020 20:41:55

US3172265

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:10:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:55:23

US3172265

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:10:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '17 Dec 2020'	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:55:23



US3172265

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:10:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:55:23

US3172265

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:10:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:55:23

US3172265

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:10:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:55:32

**US3172265**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:10:45
User entered '1'	System	18 Jan 2021 22:55:32

US3172265

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:10:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:55:42

US3172265

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:10:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '18 Jan 2021'	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:55:42

US3172265

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:10:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:55:42

US3172265

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:10:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:55:42



US3172265

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:10:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:55:55

**US3172265**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:10:45
User entered '1'	System	18 Jan 2021 22:55:55

US3172265

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:10:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:47
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Feb 2021 14:49:46

US3172265

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:10:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:47
User entered '17 Feb 2021'	Jessie Downs (b) (4) (b) (4)	18 Feb 2021 14:49:46

US3172265

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:10:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:47
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	18 Feb 2021 14:49:46

US3172265

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:10:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:47
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Feb 2021 14:49:46

US3172265

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:10:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:47
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Feb 2021 14:49:50

**US3172265**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:10:45
User entered '1'	System	18 Feb 2021 14:49:50



US3172265

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 18:50:07

US3172265

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:08

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered '25 Mar 2021'	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 18:50:07

US3172265

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:08

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 18:50:07

**US3172265**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:08**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User entered 'VISIT4'	System	25 Mar 2021 18:50:07

US3172265

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	29 Mar 2021 18:27:14

US3172265

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered '25 Mar 2021'	Jessie Downs (b) (4) (b) (4)	29 Mar 2021 18:27:14

US3172265

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered '11:33'	Jessie Downs (b) (4) (b) (4)	29 Mar 2021 18:27:14

**US3172265**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:08**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User entered '25 Mar 2021 11:33'	System	29 Mar 2021 18:27:14



US3172265

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered '36.8' C	Jessie Downs (b) (4) (b) (4)	29 Mar 2021 18:27:14

US3172265

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	29 Mar 2021 18:27:14

US3172265

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Mar 2021 18:27:14

US3172265

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered '68'	Jessie Downs (b) (4) (b) (4)	29 Mar 2021 18:27:14

US3172265

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User entered 'bpm'	System	29 Mar 2021 18:27:14

US3172265

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered '13'	Jessie Downs (b) (4) (b) (4)	29 Mar 2021 18:27:14

US3172265

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User entered 'breaths/min'	System	29 Mar 2021 18:27:14

US3172265

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered '102'	Jessie Downs (b) (4) (b) (4)	29 Mar 2021 18:27:14



US3172265

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User entered 'mmHg'	System	29 Mar 2021 18:27:14

US3172265

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered '63'	Jessie Downs (b) (4) (b) (4)	29 Mar 2021 18:27:14

US3172265

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User entered 'mmHg'	System	29 Mar 2021 18:27:14

US3172265

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12

US3172265

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12

US3172265

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 18:50:13

US3172265

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:08

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 18:50:13

US3172265

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	20 Apr 2021 13:54:58
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	29 Mar 2021 18:26:29



US3172265

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered '25 Mar 2021' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	20 Apr 2021 13:54:58
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Mar 2021 18:26:29

US3172265

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered '13:01' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	20 Apr 2021 13:54:58
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Mar 2021 18:26:29

US3172265

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:08

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User entered '25 Mar 2021 13:01'	System	20 Apr 2021 13:54:58
User entered empty.	System	29 Mar 2021 18:26:29

US3172265

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 18:50:53

US3172265

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:12
User entered 'I'	System	25 Mar 2021 18:50:53

US3172265

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	16 Apr 2021 19:31:38

US3172265

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered '16 Apr 2021'	(b) (4), (b) (6)	16 Apr 2021 19:31:38

US3172265

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Apr 2021 19:31:38



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Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 19:31:38

US3172265

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	16 Apr 2021 19:31:45

**US3172265**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 19:31:45

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 18:49:36

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:08

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:56:38
	(b) (4)	
User entered '23 Feb 2021'	Jessie Downs (b) (4)	24 Feb 2021 18:49:36
	(b) (4)	

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:08

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 18:49:36

**US3172265**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:08**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User entered 'UNBLND_DECIDE'	System	24 Feb 2021 18:49:36

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:08

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User closed query ' Sponsor Review: Per IRT, this subject received mRNA for Day 1 Dosing. Please update data or else clarify.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:13:03
Query ' Sponsor Review: Per IRT, this subject received mRNA for Day 1 Dosing. Please update data or else clarify.' answered with 'Data updated ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 21:05:22
User opened query ' Sponsor Review: Per IRT, this subject received mRNA for Day 1 Dosing. Please update data or else clarify.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 17:13:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered '06 Jan 2021'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:03:03



**US3172265**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:05:08**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4)	12 Mar 2021 20:15:02
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:16:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:08

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:03:03

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:08

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 21:04:56
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 21:04:56
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:15:02
User entered empty. WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:16:15

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:08

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered '23 Feb 2021'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:03:03

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:08

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User closed query 'Sponsor Review: Per IRT this subject was randomized to mRNA treatment assignment. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 20:17:10
Query 'Sponsor Review: Per IRT this subject was randomized to mRNA treatment assignment. Please review and reconcile.' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 14:06:30
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 14:06:05
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 14:06:05
User opened query 'Sponsor Review: Per IRT this subject was randomized to mRNA treatment assignment. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 15:22:00
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:03:03

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:08

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 14:06:05
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 14:06:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:03:03

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:08

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered 'Not Administered (NA)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	20 Apr 2021 16:17:05
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 14:06:05
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 14:06:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:03:03

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:08

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	20 Apr 2021 16:17:05
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 14:06:05
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 14:06:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:03:03



US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:08

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User entered empty.	System	12 Apr 2021 14:06:05
User entered 'I'	System	24 Feb 2021 19:03:03

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:05:08

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User entered '1'	System	20 Apr 2021 16:17:05
User entered empty.	System	12 Apr 2021 14:06:05
User entered '1'	System	24 Feb 2021 19:03:03

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:07:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:42:08
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	04 Mar 2021 20:18:02
User entered '077.8' kg reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	04 Mar 2021 20:18:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:07:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:08

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
DataPoint set to visible.	System	20 Apr 2021 16:17:05
DataPoint set to invisible.	System	12 Apr 2021 14:06:05
User entered empty.	System	24 Feb 2021 19:07:15
DataPoint set to visible.	System	24 Feb 2021 19:03:03

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:07:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:42:08
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	04 Mar 2021 20:18:02
User entered '077.8' kg reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	04 Mar 2021 20:18:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:07:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:08

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
DataPoint set to visible.	System	20 Apr 2021 16:17:05
DataPoint set to invisible.	System	12 Apr 2021 14:06:05
User entered empty.	System	24 Feb 2021 19:07:15
DataPoint set to visible.	System	24 Feb 2021 19:03:03



US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User accepted default value 'Pre-Dose (PREDOSE)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:07:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:07:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered '23 Feb 2021'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:07:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:56:38
	(b) (4)	
User entered '10:36'	Jessie Downs (b) (4)	24 Feb 2021 19:07:15
	(b) (4)	

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User entered '23 Feb 2021 10:36'	System	24 Feb 2021 19:07:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered '36.6' C	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:07:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:07:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:07:15



US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered '62'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:07:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User entered 'bpm'	System	24 Feb 2021 19:07:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered '14'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:07:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User entered 'breaths/min'	System	24 Feb 2021 19:07:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered '111'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:07:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User entered 'mmHg'	System	24 Feb 2021 19:07:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered '71'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:07:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User entered 'mmHg'	System	24 Feb 2021 19:07:15



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:07:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:42:08
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	04 Mar 2021 20:18:02
User entered '077.8' kg reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	04 Mar 2021 20:18:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:07:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:05:08

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
DataPoint set to visible.	System	20 Apr 2021 16:17:05
DataPoint set to invisible.	System	12 Apr 2021 14:06:05
User entered empty.	System	24 Feb 2021 19:07:15
DataPoint set to visible.	System	24 Feb 2021 19:03:03

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User accepted default value 'Post-Dose (POSTDOSE)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:07:15

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:07:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered '23 Feb 2021'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:07:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:56:38
	(b) (4)	
User entered '12:50'	Jessie Downs (b) (4)	24 Feb 2021 19:07:15
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User entered '23 Feb 2021 12:50'	System	24 Feb 2021 19:07:15



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered '37.0' C	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:07:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:07:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:07:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered '60'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:07:15

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User entered 'bpm'	System	24 Feb 2021 19:07:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered '16'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:07:15

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User entered 'breaths/min'	System	24 Feb 2021 19:07:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered '100'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:07:15



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User entered 'mmHg'	System	24 Feb 2021 19:07:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered '62'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:07:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User entered 'mmHg'	System	24 Feb 2021 19:07:15

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:03:31

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:08

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered '23 Feb 2021'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:03:31

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:04:55

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:04:55

US3172265

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:05:08**

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:56:38
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	24 Feb 2021 19:04:55
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
DataPoint set to visible.	System	20 Apr 2021 16:17:05
DataPoint set to invisible.	System	12 Apr 2021 14:06:05
User entered 'mRNA-1273'	System	24 Feb 2021 19:04:55
DataPoint set to visible.	System	24 Feb 2021 19:03:03

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:56:38
	(b) (4)	
User entered '23 Feb 2021'	Jessie Downs (b) (4)	24 Feb 2021 19:04:55
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered '12:20'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:04:55

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User entered '23 Feb 2021 12:20'	System	24 Feb 2021 19:04:55

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:56:38
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Jessie Downs (b) (4)	24 Feb 2021 19:04:55
	(b) (4)	

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User entered 'ONCE'	System	24 Feb 2021 19:04:55

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User entered 'INTRAMUSCULAR'	System	24 Feb 2021 19:04:55

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:00:57



US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered '23 Feb 2021'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:00:57

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered '11:36'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:00:57

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:08

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User entered '23 Feb 2021 11:36'	System	24 Feb 2021 19:00:57

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:05:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 18:58:42

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:05:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered '23 Feb 2021'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 18:58:42

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:05:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:56:38
	(b) (4)	
User entered '11:38'	Jessie Downs (b) (4)	24 Feb 2021 18:58:42
	(b) (4)	

**US3172265**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:05:08**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User entered '23 Feb 2021 11:38'	System	24 Feb 2021 18:58:42

US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:56:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Feb 2021 19:03:11



US3172265

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:08
User entered 'I'	System	24 Feb 2021 19:03:11

**US3172265**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:05:08**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	29 Mar 2021 18:22:44

US3172265

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Mar 2021 18:22:44

US3172265

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Mar 2021 18:22:44

US3172265

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:05:08

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered 'missed'	Jessie Downs (b) (4) (b) (4)	29 Mar 2021 18:22:44

US3172265

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 18:51:30

**US3172265**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:36
User entered 'I'	System	25 Mar 2021 18:51:30

US3172265

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:36
User entered 'I'	System	25 Mar 2021 18:51:30
DataPoint set to visible.	System	25 Mar 2021 18:51:30



US3172265

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 25MAR2021 is reported under OL-D29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under OL-D29 Visit on Immunogenicity Assessment page.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 04:58:14
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 25MAR2021 is reported under OL-D29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under OL-D29 Visit on Immunogenicity Assessment page.' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	20 Apr 2021 13:55:22
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 25MAR2021 is reported under OL-D29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under OL-D29 Visit on Immunogenicity Assessment page.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 08:31:06
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 18:52:59

US3172265

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:08

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered '25 Mar 2021'	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 18:52:59

US3172265

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:05:08

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 18:52:59

**US3172265**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:05:08**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User entered 'OLD29'	System	25 Mar 2021 18:52:59

US3172265

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	20 Apr 2021 13:53:37

US3172265

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered '25 Mar 2021'	Jessie Downs (b) (4) (b) (4)	20 Apr 2021 13:53:37

US3172265

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered '11:33'	Jessie Downs (b) (4) (b) (4)	20 Apr 2021 13:53:37

US3172265

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User entered '25 Mar 2021 11:33'	System	20 Apr 2021 13:53:37



US3172265

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered '36.8' C	Jessie Downs (b) (4) (b) (4)	20 Apr 2021 13:53:37

US3172265

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	20 Apr 2021 13:53:37

US3172265

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Apr 2021 13:53:37

US3172265

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered '68'	Jessie Downs (b) (4) (b) (4)	20 Apr 2021 13:53:37

US3172265

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User entered 'bpm'	System	20 Apr 2021 13:53:37

US3172265

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered '13'	Jessie Downs (b) (4) (b) (4)	20 Apr 2021 13:53:37

US3172265

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User entered 'breaths/min'	System	20 Apr 2021 13:53:37

US3172265

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered '102'	Jessie Downs (b) (4) (b) (4)	20 Apr 2021 13:53:37



**US3172265**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:05:08**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User entered 'mmHg'	System	20 Apr 2021 13:53:37

US3172265

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered '63'	Jessie Downs (b) (4) (b) (4)	20 Apr 2021 13:53:37

US3172265

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User entered 'mmHg'	System	20 Apr 2021 13:53:37

US3172265

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13

US3172265

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:05:08

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13

US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User accepted default value 'Pre-Dose (PREDOSE)'	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 19:04:50

US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 19:04:50

US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered '25 Mar 2021'	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 19:04:50



US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered '11:33'	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 19:04:50

US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User entered '25 Mar 2021 11:33'	System	25 Mar 2021 19:04:50

US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered '36.8' C	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 19:04:50

US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 19:04:50

US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 19:04:50

US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered '68'	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 19:04:50

**US3172265**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:05:08**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User entered 'bpm'	System	25 Mar 2021 19:04:50

US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered '13'	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 19:04:50



US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User entered 'breaths/min'	System	25 Mar 2021 19:04:50

US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered '102'	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 19:04:50

US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User entered 'mmHg'	System	25 Mar 2021 19:04:50

US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered '63'	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 19:04:50

US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:05:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User entered 'mmHg'	System	25 Mar 2021 19:04:50

US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User accepted default value 'Post-Dose (POSTDOSE)'	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 19:04:50

US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 19:04:50

US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 19:04:50



US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 19:04:50

US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User entered empty.	System	25 Mar 2021 19:04:50

US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 19:04:50

US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 19:04:50

US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 19:04:50

US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 19:04:50

**US3172265**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:05:08**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User entered empty.	System	25 Mar 2021 19:04:50

US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 19:04:50



US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User entered empty.	System	25 Mar 2021 19:04:50

US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 19:04:50

US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User entered empty.	System	25 Mar 2021 19:04:50

US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered empty.	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 19:04:50

US3172265

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:05:08

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User entered empty.	System	25 Mar 2021 19:04:50

US3172265

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 18:53:26

US3172265

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:05:08

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:38
User entered '25 Mar 2021'	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 18:53:26

US3172265

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:31
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	29 Mar 2021 18:25:23



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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:31
User entered 'Other (OTHER)'	Jessie Downs (b) (4) (b) (4)	29 Mar 2021 18:25:23

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:31
User entered 'Subject first MRNA dose was 21AUG2020 and subject second dose was taken 23FEB2020.'	Jessie Downs (b) (4) (b) (4)	29 Mar 2021 18:25:23

US3172265

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
DataPoint set to visible.	System	12 Apr 2021 14:06:05
User entered empty.	System	29 Mar 2021 18:25:23
DataPoint set to invisible.	System	25 Mar 2021 18:51:30

US3172265

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:31
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Mar 2021 18:25:23

US3172265

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:31
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Mar 2021 18:25:23

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User entered empty.	System	29 Mar 2021 18:25:23

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:31
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Mar 2021 18:25:23

US3172265

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User entered empty.	System	29 Mar 2021 18:25:23



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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:05:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User entered empty.	System	29 Mar 2021 18:25:23

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Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:31
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	20 Apr 2021 13:53:56

US3172265

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:31
User entered '25 Mar 2021'	Jessie Downs (b) (4) (b) (4)	20 Apr 2021 13:53:56

US3172265

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:05:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:31
User entered '13:01'	Jessie Downs (b) (4) (b) (4)	20 Apr 2021 13:53:56

**US3172265**

**Folder: OL-D29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:05:08**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User entered '25 Mar 2021 13:01'	System	20 Apr 2021 13:53:56

US3172265

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:05:08

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:27:31
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Mar 2021 18:54:06

**US3172265**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:05:08**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:55:13
User entered 'I'	System	25 Mar 2021 18:54:06

US3172265

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:05:08

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:02:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 13:59:36



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:18:07
	(b) (4)	
User closed query 'Per MM: Please specify term.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:55:01
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Urticarial rash - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 23:11:41
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 23:11:41
	(b) (4)	
Data point term sent to Coder	System	04 Nov 2020 19:39:53
Query 'Per MM: Please specify term.' answered with '(CONSISTENT WITH HIVES)' (Site from DM).	Mariete Rendon (b) (4)	04 Nov 2020 19:39:19
	(b) (4)	
Coding entries removed.	Mariete Rendon (b) (4)	04 Nov 2020 19:38:55
	(b) (4)	
User entered 'SKIN RASH (consistent with HIVES) (ARMS, LEGS, CHEST, AND BACK)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	04 Nov 2020 19:38:55
	(b) (4)	
User opened query 'Per MM: Please specify term.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 17:38:03
User closed query 'Per CDM: To help clarify the clinical significance of the event of SKIN RASH (HIVES) (ARMS, LEGS, CHEST, AND BACK) and possible association with the administration of investigational product and/or study procedure, if this is related to the site of administration, please update the Adverse Event to 'INJECTION SITE SKIN RASH (HIVES) (ARMS, LEGS, CHEST, AND BACK)' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 21:09:59
Query 'Per CDM: To help clarify the clinical significance of the event of SKIN RASH (HIVES) (ARMS, LEGS, CHEST, AND BACK) and possible association with the administration of investigational product and/or study procedure, if this is related to the site of administration, please update the Adverse Event to 'INJECTION SITE SKIN RASH (HIVES) (ARMS, LEGS, CHEST, AND BACK)' answered with 'Not an injection site reaction.' (Site from DM).	Mariete Rendon (b) (4)	12 Oct 2020 15:34:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: To help clarify the clinical significance of the event of SKIN RASH (HIVES) (ARMS, LEGS, CHEST, AND BACK) and possible association with the administration of investigational product and/or study procedure, if this is related to the site of administration, please update the Adverse Event to 'INJECTION SITE SKIN RASH (HIVES) (ARMS, LEGS, CHEST, AND BACK)' ' (Site from DM).	(b) (4), (b) (6)	11 Oct 2020 01:14:06
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) (b) (4)	08 Oct 2020 10:45:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 10:45:31
User closed query 'Per DM CLR: Please specify the location of SKIN RASH (HIVES) (e.g., Generalized, Both Arms, Right Leg, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 18:17:43
Data point term sent to Coder	System	30 Sep 2020 19:26:48
User entered 'SKIN RASH (HIVES) (Arms, legs, chest, and back)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 19:26:05
Query 'Per DM CLR: Please specify the location of SKIN RASH (HIVES) (e.g., Generalized, Both Arms, Right Leg, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'Data updated' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 15:47:08
Data point term sent to Coder	System	30 Sep 2020 15:47:02
Coding entries removed.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 15:46:52
User entered 'SKIN RASH (HIVES) Generalized' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 15:46:52

US3172265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please specify the location of SKIN RASH (HIVES) (e.g., Generalized, Both Arms, Right Leg, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 02:35:34
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) (b) (4)	08 Sep 2020 11:54:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 11:54:53
Data point term sent to Coder	System	01 Sep 2020 14:03:20
User entered 'SKIN RASH (HIVES)'	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 14:03:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 14:03:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 14:03:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 14:03:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '22 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 14:03:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:18:07
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:04:03
User entered '23:00' reason for change: Data Entry Error	Mariete Rendon (b) (4)	01 Sep 2020 14:04:03
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:03:11
User entered empty.	Mariete Rendon (b) (4)	01 Sep 2020 14:03:11
	(b) (4)	



**US3172265**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:05:08**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 23:00'	System	01 Sep 2020 14:04:03
User entered empty.	System	01 Sep 2020 14:03:11

US3172265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 14:03:11

US3172265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '25 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 14:03:11

US3172265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:18:07
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:04:03
User entered '05:00' reason for change: Data Entry Error	Mariete Rendon (b) (4)	01 Sep 2020 14:04:03
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:03:11
User entered empty.	Mariete Rendon (b) (4)	01 Sep 2020 14:03:11
	(b) (4)	

**US3172265**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:05:08**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 05:00'	System	01 Sep 2020 14:04:03
User entered empty.	System	01 Sep 2020 14:03:11

US3172265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 14:03:11

US3172265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 14:03:11

US3172265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 14:03:11



US3172265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 14:03:11

US3172265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 14:03:11

US3172265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 14:03:11

US3172265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 14:03:11

US3172265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 14:03:11

US3172265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 14:03:11

US3172265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 14:03:11

US3172265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 14:03:11



US3172265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 14:03:11

US3172265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Related (RELATED)'	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 14:03:11

US3172265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:18:07
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 18:24:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Sep 2020 18:24:58
User entered 'Related (RELATED)' reason for change: Data Entry Error	Jessie Downs (b) (4)	09 Sep 2020 18:24:58
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 14:03:11
User entered empty.	Mariete Rendon (b) (4)	01 Sep 2020 14:03:11
	(b) (4)	

US3172265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User closed query 'Per CDM: "Action taken with investigational product is Investigational Product Withdrawn". However Exposure form and Dosing Discontinuation form is not updated under End of study folder. Please review and update else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 17:21:38
Query 'Per CDM: "Action taken with investigational product is Investigational Product Withdrawn". However Exposure form and Dosing Discontinuation form is not updated under End of study folder. Please review and update else clarify. Thank you' answered with 'dATA UPDATED' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 21:38:59
User opened query 'Per CDM: "Action taken with investigational product is Investigational Product Withdrawn". However Exposure form and Dosing Discontinuation form is not updated under End of study folder. Please review and update else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 04:17:09
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 14:03:11

US3172265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

None

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 14:03:11

US3172265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '1'	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 14:03:11

US3172265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 14:03:11

US3172265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 14:03:11



US3172265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 14:03:11

US3172265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	01 Sep 2020 14:03:11

US3172265

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:05:08

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	01 Sep 2020 14:03:11

**US3172265**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:05:08**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Sep 2020 14:03:11

US3172265

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 11 Aug 2021 22:05:08**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:02:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 21:37:31

US3172265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:08

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:18:07
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 22:56:53
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 22:56:53
	(b) (4)	
Data point term sent to Coder	System	30 Sep 2020 15:59:34
Coding entries removed.	Mariete Rendon (b) (4)	30 Sep 2020 15:59:10
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 07:45:40
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 07:45:40
	(b) (4)	
Data point term sent to Coder	System	31 Aug 2020 21:39:28
User entered 'LORATTADINE'	Jessie Downs (b) (4)	31 Aug 2020 21:38:39
	(b) (4)	

US3172265

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:05:08**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 21:38:39

US3172265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:18:07
	(b) (4)	
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 18:18:33
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'Data updated' (Site from DM).	Mariete Rendon (b) (4)	30 Sep 2020 15:59:16
User entered 'SKIN RASH (Hives)' reason for change: Data Entry Error	(b) (4)	30 Sep 2020 15:59:10
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 08:56:50
User entered 'SKIN RASH'	Jessie Downs (b) (4)	31 Aug 2020 21:38:39
	(b) (4)	



US3172265

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:05:08**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '10'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 21:38:39

US3172265

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:05:08**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 21:38:39

US3172265

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:05:08**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 21:38:39

US3172265

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:05:08**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'once (ONCE)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 21:38:39

US3172265

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:05:08**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 21:38:39

US3172265

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:05:08**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 21:38:39

US3172265

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:05:08**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 21:38:39

US3172265

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:05:08**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '24 Aug 2020'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 21:38:39



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:05:08**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '0'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 21:38:39

US3172265

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:05:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 21:38:39

US3172265

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:05:08**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '24 Aug 2020'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 21:38:39

US3172265

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:05:08**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 21:38:39

**US3172265**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:05:08**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 21:38:39

US3172265

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:05:08**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 21:38:39

US3172265

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:05:08**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 21:38:39

US3172265

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 22:05:08**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:18:07
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	03 Sep 2020 16:11:47
	(b) (4)	



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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:05:08

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:13:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered '24 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 21:38:18

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:05:08

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:13:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User entered 'AE (specify) (ADVERSE EVENT)'	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 21:38:18

US3172265

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:05:08

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:13:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:18:07
User closed query 'Per CDM: please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 13:37:28
Query 'Per CDM: please record AE record number instead of details ' answered with 'Data updated as per query request.' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 20:11:12
User entered 'A/E #1.' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 20:10:42
User entered 'DUE TO SKIN RASH (HIVES) A/E #1.' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	18 Nov 2020 20:10:28
User opened query 'Per CDM: please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 13:25:06
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	09 Sep 2020 21:39:37
User entered 'Due to skin Rash (Hives) A/E.' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 21:39:37
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	09 Sep 2020 21:38:18
User entered empty.	Mariete Rendon (b) (4) (b) (4)	09 Sep 2020 21:38:18